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MARCH 2016

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p. 6

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VP, manufacturing and technical operations, Janssen

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White- And Blue-Collar Leadership In Pharma Outsourcing

LOUIS GARGUILO Executive Editor

What do biotechnology and pharmaceutical sponsors want most from their contract development and manufacturing service providers? Today that answer might be summed up as: "White- and Blue-Collar Leadership." Allow me to explain.

During last year's CMO Leadership Awards ceremony, I thought the following: "Despite the vast industry experience and brainpower of the scientists, engineers, managers, and executives in this ballroom, the service providers gathered here represent the real blue-collar workforce of the biopharma industry" — blue collar in every positive connotation of the term.

As I explained in a subsequent article, these are the hard-working men and women, often unbeknownst and unacclaimed, who wake up each day around the globe to keep projects and materials flowing and provide the services and solutions the rest of the industry – and patients ultimately – count on. Along with the great men and women at their sponsors' facilities, these are the people who help put the "make" in "making drugs."

As the year progressed, though, we increasingly heard biotech and pharma sponsors talk about obtaining a higher level of strategic leadership from their service providers and suppliers. CMOs should now feel confident, sponsors are saying, and add "white-collar" leadership to overall relationships, as well as guidance for specific projects. In fact, at an Outsourcing Pharma Conference during the year, the CEO of a CMO said, "I've been astonished at the use of the word 'partner' more recently; sponsors actually mean it." Another CEO put it this way: "We're reaching an interesting point where the service-provider industry needs to make a decision: Are we going to lead?"

Moving to this year's CMO Leadership Awards, and this supplement to *Life Science Leader*, we've listened carefully to both sides of the sponsor-provider dialogue. For the first time, we've partnered with Industry Standard Research (ISR) to home in on the specific attributes the bio and pharma industries value in their CMOs: quality, reliability, capabilities, expertise, and compatibility. We've also taken into account that while all sponsors look for these qualities in some manner and degree, your needs and approach vary more than ever. To capture this, we've broken down the awards into the sponsor categories of: Big Pharma, Small Pharma, or Overall (combined Big and Small Pharma).

There's more. We've also made an adjustment from perception-based metrics to experiential data, ensuring our results are truly aligned with direct sponsor experience. This year, award recipients can see more clearly reflected in their crystalline awards words like "partner" and "leader."

Is there an overriding focus in outsourcing in 2016? If I had to pick one, I'd go back to a fundamental activity: project management. More outsourcing, more complicated products and processes, wider global and multivendor partnerships, and extended supply chains all call for elevated and enlightened project management. One of our articles in this issue (p. 28) dives into this subject. (Spoiler alert: we draw an unexpected conclusion.) I hope you'll enjoy all the articles within, as well as reading the lists of who's the best of the best in our industry. I'd also like to send out a special thank-you to Janssen's Remo Colarusso for working with me on the feature article. L

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LIFE SCIENCE LEADER
5340 Fryling Rd., Suite 300 / Erie, PA 16510-4672
Telephone: 814 897 7700 / Fax: 814 899 4648
WWW.LIFESCIENCELEADER.COM

SVP OF PUBLISHING/PRODUCT DEVELOPMENT
Jon Howland / Ext. 203
jon.howland@lifescienceconnect.com

VP OF CONTENT
Ed Hess
ed.hess@lifescienceconnect.com

EDITORIAL DIRECTOR
Dan Schell / Ext. 284
dan.schell@lifescienceleader.com

CHIEF EDITOR
Rob Wright / Ext. 140
rob.wright@lifescienceconnect.com

EXECUTIVE EDITORS
Wayne Koberstein
wayne.koberstein@lifescienceleader.com

Louis Garguilo
louis.garguilo@lifescienceconnect.com

Ed Miseta
ed.miseta@lifescienceconnect.com

Trisha Gladd
trisha.gladd@lifescienceconnect.com

SENIOR DIRECTOR OF PUBLISHING
Perry Rearick
perry.rearick@lifescienceconnect.com

VP OF AUDIENCE DEVELOPMENT
Michael Bennett
michael.bennett@lifescienceconnect.com

PRODUCT DIRECTOR
Jenell Skemp
jenell.skemp@lifescienceconnect.com

PROJECT MANAGER
Megan Rainbow
megan.rainbow@lifescienceconnect.com

DIRECTOR, LIFE SCIENCE TRAINING INSTITUTE
Bill Beyer
bill.beyer@lifescienceconnect.com

PUBLISHER, CLINICAL & CONTRACT RESEARCH
Sean Hoffman / 724 940 7557 / Ext. 165
sean.hoffman@lifescienceconnect.com

PUBLISHER/BIOPHARM & LAB
Shannon Primavere / Ext. 279
shannon.primavere@lifescienceconnect.com

PUBLISHER/OUTSOURCING
Cory Coleman / Ext. 108
cory.coleman@lifescienceconnect.com

ENGAGEMENT MANAGER
Kevin Morey
kevin.morey@lifescienceconnect.com

GROUP PUBLISHER/OUTSOURCING
Ray Sherman / Ext. 335
ray.sherman@lifescienceconnect.com

BUSINESS DEVELOPMENT MANAGER
Mike Barbalaci / Ext. 218
mike.barbalaci@lifescienceconnect.com

SR. ACCOUNT EXECUTIVE
Scott Moren / Ext. 118
scott.moren@lifescienceconnect.com

PRODUCTION DIRECTOR
Lynn Netkowicz / Ext. 205
lynn.netkowicz@jamesonpublishing.com

MANAGE SUBSCRIPTIONS
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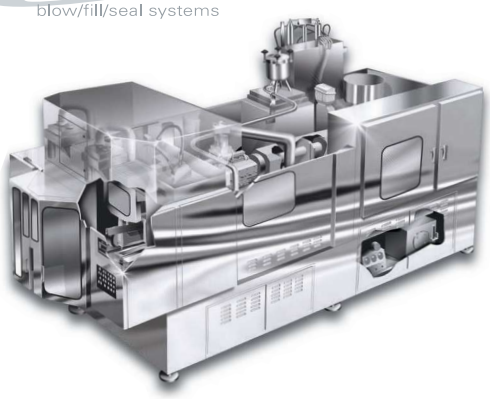

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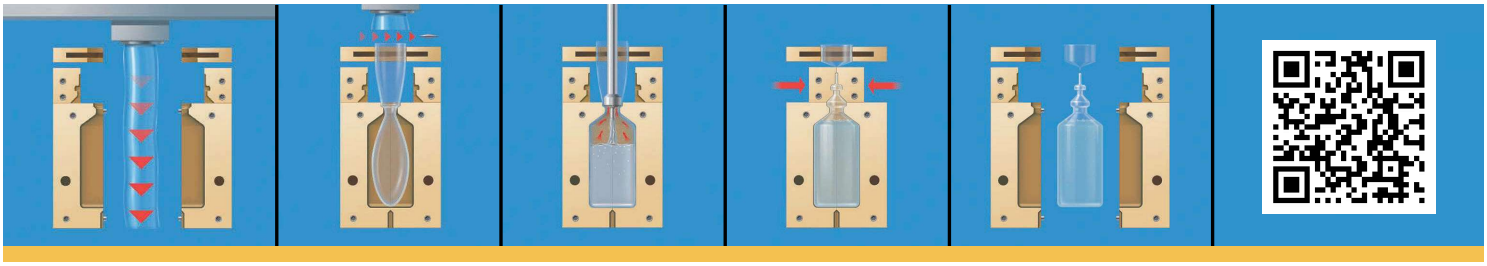

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RELIABILITY ROOMS AND SUPPLY CHAINS AT JANSSEN

By L. Garguilo

REMO COLARUSSO
VP, manufacturing and technical operations, Janssen

RELIABILITY ROOMS And SUPPLY CHAINS At Janssen

LOUIS GARGUILO Executive Editor, Outsourced Pharma @Louis_Garguilo

Remo Colarusso, VP, manufacturing and technical operations at Janssen (pharmaceutical companies of Johnson & Johnson), knows what you measure is as important as how you measure, and cross-functional review of the results can be as essential as the results themselves. He also knows that nowadays, Janssen appears in good shape in all four of these quadrants.

For proof of this, Janssen, like other pharma companies, looks to supply chain measurements such as LIFRs — line item fill rates (more on LIFR specifically in a moment.) Executives at other pharmas might be envious of the statistics Colarusso sees: obtaining or exceeding 99.5 percent LIFR for core products; 90 percent reduction in missed orders since 2011.

Colarusso, a 27-year veteran of J&J, spoke exclusively with *Life Science Leader CMO Supplement* about a main driver of these results. Below he describes how Janssen's "Reliability Rooms" are elevating the art of measuring and improving reliability and quality throughout the supply chain. And while some of this information may prove valuable to other pharma companies, external partners should take equal notice — a "room" could be heading your way soon.

Metrics To Build On

"Reliability Rooms aren't just a room and a place," says Colarusso. "They're a business performance management process." We'll take a look at that process closely, but in essence, Reliability Rooms started in 2011 as, and still include, physical areas established at each of the company's 20-plus manufacturing locations. Within these rooms Janssen gathers an array of supply chain metrics for finished drug products and APIs, available for cross-functional teams to review, digest together, and take specific actions on.

A mainstay of that data for drug product plants has been the LIFR mentioned earlier. This can be defined as an overall measure of the ratio of actual orders filled in terms of all the fulfillment lines for a product. For example, if three of five lines of an order are filled, the LIFR would be 60 percent. Looked at from the

IN PHARMA, THERE'S LITTLE DAYLIGHT BETWEEN RELIABILITY AND QUALITY

As a convicted wordsmith, or perhaps more positively because words do matter, it's of interest to me how the pharmaceutical industry interchanges these two words: reliability and quality. This was again brought to mind when talking with Remo Colarusso, VP of manufacturing and technical operations, about Janssen's Reliability Rooms. Along with the allure of alliteration, there was certainly more to Janssen's decision to use "reliability" instead of "quality" for this important supply chain initiative, wasn't there?

Before asking Colarusso, let's consider: Where are the Reliability Control (RC) or Reliability Assurance (RA) titles to match those of Quality Control (QC) and Quality Assurance (QA)? This is no trivial pursuit. A more stringent division of these two words might help in the continuing efforts to alleviate product shortages and to market drugs of the highest quality standards. Reliability is to supply chain performance as quality is to individual products (within the chains). Yes, they are intrinsically connected, but does our industry make the distinction clear enough to improve both sides?

A Reluctant Division

I ask Colarusso if the pharmaceutical industry's intoning of quality – no doubt for good reason – in some degree detracts from supply chain management and actually impacts overall reliability. Let's say Colarusso doesn't quite take the bait. He does, though, take the thought seriously, and provides some valuable insight.

"At Janssen, like other companies, it is very much both," he replies. "We start from our long history of being a 'high quality organization.' We view that, first, as meaning we are a fully regulatory-compliant company. Yes, there has been so much talk and emphasis around quality in the industry, and that's been no different for us. I'd agree that, comparatively, perhaps the broader supply chain reliability has not been as emphasized."

If there has been any under-representation of reliability as the overall process of the supply chain, Janssen is addressing it via the Reliability Rooms. That initiative will also reach CMOs and other external partners. Considering outsourcing and external supply chains, which as we know have become essential elements of drug manufacturers' business models, the discussion here seems to tilt heavily to the topic of quality.

However, I'd submit that with the now very experienced and well-established cGMP-compliant CMOs – which have undergone years of FDA and other regulatory inspections – quality is actually less of a concern than the overall reliability of product delivery. Here's what I mean: As CMOs and other pharma partners continue to grow in importance, will they be able to effectively manage projects, handle compressed development and delivery timelines, coordinate larger alliances (with various product lines), and plan sufficiently for steady (reliable) supplies of starting and raw materials? Can they keep costs down and their margins up to stay viable? Do they understand their position within the chain for each product they provide services for? These are reliability questions of growing concern.

"We talk about how both quality *and* reliability are foundational elements to our success," says Colarusso, "and that has to include our partners. Note that it is quality and reliability. Because of that dual emphasis, I think everyone understands these are not the same, but also that there is not an emphasis on one over the other. To me, they remain synergistic, and that's what we stress as an organization and in terms of overall business performance," Colarusso adds. "The reality is, the reliability of the pharma supply chain is still most heavily impacted by quality. One quality problem in the chain can quickly lead to a supply disruption."

Partners In Performance

I think we would all agree that there can only be one ultimate measurement. The supply chain is either reliable or it is not. It either consistently delivers the requisite amount of goods (on time) that meet quality standards or it doesn't. If it is not, or it doesn't, external partners have become as important as internal resources in rectifying the situation.

"An older term was 'supplier performance management,' wasn't it?" Colarusso asks rhetorically about external partners. "That kind of signifies how procurement groups throughout the industry would look at outsourcing. It was more about the 'buy' – 'Here's an order, deliver our product by this date at this price.'

"At Janssen, we realize that some of our partners are doing sophisticated manufacturing for us," Colarusso continues. "We want them to continue to get better because that means we get better. Their reliability to us can translate to our reliability to our customers. That's why we are moving forward in sharing more of our processes that have demonstrated improved performance."

Along with this process sharing, what advice might Colarusso offer other pharma companies? "The best advice I could give any organization is to first make sure any relationship you are about to enter makes sense for your business. You've got to be consistent with your business strategy," he replies. As an example, he says it's good policy to utilize your core strengths and technologies, and outsource what you may not be focused on as a company. He also says that, to the extent possible, sponsors should provide CMOs and suppliers with meaningful opportunities to become true partners. "Both sides need to move away from transactional-based thinking. You should have the perspective that you both win, by both winning."

What about advice to the service providers for ensuring they become reliable partners? "It's very similar," he says. "Service providers also need to look for the customers willing to provide the opportunity to establish those win-win relationships. Next, I'll go back to the original discussion we had on this. It is paramount for any company in the pharmaceutical industry, no matter external or internal or where they are in the process, to focus relentlessly on the quality of supply and the reliability of the entire chain. Those two are foundational. You can't do anything else without that."

opposite perspective, we can see how important this measurement really is: 40 percent of a specific product did not get to certain customers, for example hospitals, fulfillment centers ... and more and more directly to patients. "We count all the lines within all the orders in a specified time period," explains Colarusso. "For some key products we've consistently reached 99.5 percent. While we strive to be 100 percent, that's a tremendous accomplishment."

But it's not all LIFR. All told, Janssen has identified a basket of 21 standard, end-to-end reliability metrics, including these categories and examples: DESIGN (on time product launch), PLAN (inventory on target), SOURCE (material supplier quality), MAKE (on time in full), DELIVER (LIFR), and RISK MANAGEMENT (supplier readiness). Colarusso comments: "None of these is revolutionary; they are pretty standard areas that everyone measures. But when it came to reliability of supply specifically, we wanted to measure everything important, from demand forecast variability to deviations and quality events, and measure them all the time. What is really important for us is, first, we have clearly defined and brought together what exactly we're going to stress in our metrics, and thus what drives behaviors. Second, we've ensured these metrics are fully standardized across all of our plants globally so that when we applied automation, they could roll up in the same way. We can now clearly compare A versus B, as in this plant's doing better than that, or this plant is learning from the other."

Let's look then, at the Reliability Rooms of today, their automation, and also get back to the business process Colarusso started us off with.

A Room With A View

Janssen has been tuning this "performance management process" since its inception in 2011, when Reliability Rooms were first rolled out. For one — like most everything else nowadays — the data is easily accessed via electronic dashboards. But that doesn't mean employees, managers, and executives can again hunker down in their respective cubicles, plants, offices ... and silos.

"What's perhaps noteworthy industrywide," says Colarusso, "is how we manage this. We've set a strict agenda of metrics, but, as importantly, we've prescribed a process for their review in a fully cross-functional format. It isn't just manufacturing or engineering, or

> ***"This all hinges on our standardization of the metrics across facilities."***
>
> **REMO COLARUSSO**
> VP, manufacturing and technical operations, Janssen

maintenance and quality; it has to be all things together."

To accomplish this, according to Colarusso, Janssen divides the metrics into "several tiers of information," with each tier having a different group of people who review the metrics at different intervals. For instance, the basic tier pertains to factory shift workers who meet daily for on-the-spot, proactive performance reviews and discussions on avoiding events that might impair the ability to deliver product on time. The next tier of information is reviewed weekly and monthly by management. "We're specific around who's involved and how meetings are conducted," says Colarusso. "We're just as clear on how that information rolls up and the actions, roles, and responsibilities of the various levels. That's what's really improved for us."

And let's not fail to give recognition to the advances that online access, data clouds, and formatting for mobile devices afford users of the Reliability Rooms. According to a Janssen Supply Chain Reliability document Colarusso shared with us, an "Automated Reliability Metric Dashboard" provides full transparency into the 21 reliability metrics, providing senior leadership with the ability to track in real time and predict performance across supply chains, markets, and products. This should help executives develop insights into the cumulative improvements and strategies across the network.

"That automation has provided someone like me the ability to get into a Reliability Room and drill down to a particular plant or a particular business unit, and then call up all the reliability metrics around that unit," says Colarusso. "So the access is beneficial. But again, I want to stress this all hinges on our standardization of the metrics across facilities. The metrics are here, so are the cross-functional teams to discuss them, all revolving around the best quality and reliability for the customer."

A Room Of Your Own

There's one area in this reliability management process where Janssen has some work left to do. Colarusso informs me that as of yet, Janssen's CMOs and other external suppliers don't quite have a seat within the Reliability Rooms. "That integration of CMOs and key external partners is a key next step," he says.

Currently, Janssen utilizes an overall metric for contract companies called "On-Time In-Full" to track supplier quality and reliability. "We do get into specifics with each supplier, of course," says Colarusso, "but when we order a certain quantity of API, for example, 'Did it come into us on time, and in full quantity and quality?' is the overarching question." Colarusso is quick to add, though, that in fact this measurement drives the same type of key metrics as those on the drug product side. "It's basically an analog for API and raw materials to the LIFR for finished products." Well enough for now, but Colarusso and Janssen look

forward to fully assimilating the CMOs directly into Reliability Rooms for a tighter-managed integration of the entire supply chain.

"We're working with our partners now, and there are options on the table," says Colarusso. A lot will be determined by the sophistication that's necessary or required for each vendor. "Different vendors have different capabilities," he explains. "Now our sites have the process laid out and the data synergized so it can be rolled up. We would envision ultimately doing that for our partner CMOs."

Colarusso envisions this step starting out much like the original Reliability Rooms, as "initially something simple and manual." Janssen will study how and what adds the most value and tweak the process until it too leads to useful day-to-day data and metrics that efficiently roll up to senior management. "To me, that's what I'd call the real automation: The efficiency of the process to get started."

And finally, while on the subject of CMOs and outsourcing in general, I ask Colarusso how important this "external factor" is for Janssen. Is outsourcing growing as we've heard from other pharma companies? Is there a model or strategy for outsourcing — for example, diversify the chain or concentrate on fewer and bigger partnerships?

"We fall more in line with the strategic partnership model," replies Colarusso. "We try to focus on bringing that total number of service providers down, but of course we're never fully successful. One reason is because there's a lot of licensing going on all the time, and those licenses typically come with CROs, CDMOs, and CMOs attached." Colarusso says another factor is the consistent need for new partners with new and advanced technologies and capabilities based on the new drug programs at Janssen.

"Things change depending on your activity," Colarusso concludes. "Overall, our strategy is centered around building the supply chain from whatever is best for that business. That's the mission. Whether that involves internal or external resources, it has to do with specific product, the technology utilized by the product, what we consider core technologies we think we're better at, or what technologies might be core to key partners."

What is certain is that whoever gets to work with Janssen — be it on the inside or externally — should be fully prepared for the 21 key measurements, serious cross-functional (and intercompany) review, and proactive actions … and to spend a fair amount of time in the Reliability Room. L

Did You Hear The One About the **Supply Chain Infrastructure?**

LOUIS GARGUILO Executive Editor, Outsourced Pharma @Louis_Garguilo

Building a reliable supply chain infrastructure; technology transfer challenges; scale-downs and scale-ups; CMO realities vs. pharma requirements; biotechs, startups, and virtual business models and their financing; small and large molecule strategies; global or domestic outsourcing; measuring everything that moves and breathes; risk mitigation and risk-sharing assessments ... we are a serious lot, with a lot on our minds.

Therefore, from time to time, all of us in this philoprogenitive pharmaceutical industry can use a dose of levity. In fact, I think we find those of us in the outsourcing-related sectors, if maybe a little nerdy (hey, speak for yourself), are a pretty fun-loving and good-natured group of individuals.

That includes Kent Pryor, chief operating officer of ZZ Biotech. He starts with the company name. It takes the "Zs" from the first letters of the last names of neurology researcher Berislav Zlokovic and financier Selim Zilkha. "However," Kent says, "people wonder if we are fans of the rock group ZZ Top. Well, in fact, we make our headquarters in Houston where ZZ Top was formed in 1969."

Pryor once found himself on a stage seated as a panelist at an outsourcing conference, along with representatives from much bigger powers such as Pfizer and Sandoz. Representing his bootstrapped biotech, Pryor at first appeared miscast for this discussion on "How to protect yourself by building an outsourcing infrastructure." He ended up stealing the show, as they say. We'll listen in to the insight and wit from this representative of a company that relies on global outsourcing for the clinical and commercial development of a new drug. I'll add some asides. And Ray Kaczmarek, VP commercial manufacturing and supply chain operations, Pacira Pharmaceuticals, another panelist that day, also will interject to provide some perspective.

> *"We have a single product on a tight budget. I'm involved with everything, the glue that holds the activities together. I hope I avoid getting stuck."*
>
> **KENT PRYOR**
> COO, ZZ Biotech

WHY DID THE SUPPLY CHAIN CROSS THE STREET?

Here's how Kent introduced himself: "I'm the chief operating officer at ZZ Biotech. We're *almost* as big as Pfizer ... We have two employees. Half the company is sitting right here. We're going to have different perspectives on what infrastructure means. I've worked in small public companies and small private companies, but ZZ Biotech is the smallest. In a nutshell, we fit in a nutshell."

Pharma makes headlines when they talk about their supply chains. The Shire outsourcing model comes to mind. I recently wrote an article in *OutsourcedPharma.com* on Janssen's approach. Gilead's contract with Cambrex to make the API for their Hep C drug was of interest to most everybody. But what of the growing cadre of biotechs, startups, and virtual companies like ZZ Biotech? What does the supply chain mean for them?

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Back to that panel discussion, the moderator skipped through thoughts on subjects such as "alliance management," and the processes in determining how to manage external outsourcing infrastructures. Pfizer and Sandoz representatives had enlightening descriptions, some best practices, and interesting anecdotes. All the while, panelist Pryor listened intently, wearing the thin shadow of a Cheshire cat's smile. He was asked to explain the different plans for establishing an outsourcing infrastructure if your goal is to take a program to Phase 2 and sell it, versus taking it through commercialization.

"I don't know what my plan is," Kent said to some laughter. "Maybe somebody will buy us after we finish Phase 2 or after we finish Phase 2-B or maybe after we pursue another indication. Or we might take it all the way. But we are not going to build in a bigger infrastructure than what we need for ourselves to drive the project today. Right now, if we don't need it, we aren't building it.

"That's not to say I don't think about different strategies," he added. "I think about our strategy every day. I know the types of people I would need to hire at different times in the development process, as we go as far down this road as it makes sense to go."

INTERMEZZO

Let's move the spotlight to Kaczmarek. He amplifies some of what Pryor says, but also tells us of an experience that saw some of Pryor's approach lead to an approved commercial product.

"When I started Pacira, I can truly tell you we weren't looking at our long-term infrastructural pieces whatsoever. We were trying to survive day-to-day. Then, when in early 2012 we got approval for our drug, the only problem was we couldn't even manufacture it at scale yet. In other words, we had to figure out how to make it, because we were starting to sell it. What are you going to do in that situation? Well, you simply start driving that tactical piece as hard as you can to gain your supply chain."

Kaczmarek continues: "But as you grow and gain experience as a company, you start to understand how important it is to look at your integration of outsourcing, to manage that strategic profile, and understand the various capacities. You may start by designating someone within your organization to focus on the long-term strategy. Or, if you're just doing it step-by-step – even as a virtual exercise – it's critical to think about how the pieces are to be managed.

"Yes, it's hard to look out past what you're dealing with on a daily basis. At the same time, there are so many potential faults at the back half of the process you can address earlier in your phases. This will help provide a successful commercial launch later on.

"Even if you're looking to sell off the product during phase study, you need a scalable process. You want to ensure you put yourself in a position to sell profitably. Have you set milestones up? Internal oversight and consultants can help align a supply chain for small companies. I've been with big players in the past like Wyeth and Bayer; they all have those strategic plans and those planners. They are focused on how that whole product line is going to be developed and utilized, from nuts to bolts. These are the differences between big and small companies, but the small companies should plan ahead as much as possible."

ON WITH THE SHOW

Returning to Pryor, the next question he had to handle was on "alliance management." I thought he might say something poetic like, "Alliance shmalliance!" Here's what he actually said.

"I don't have a group for handling that sort of thing. Perhaps here there are a few minor differences between Pfizer and ZZ Biotech. We have a single product. I believe they have more than that. Our company was set up to develop this product. We don't have many different things going on at different stages. We're either manufacturing that drug, or we're not manufacturing that drug this week. We're either doing a stability study on that drug or not doing a stability study. I make use of consultants who have specific backgrounds in specific areas as needed.

"I actually just got back from Australia, where I was doing a site audit of the biomanufacturing facility we're going to use. I went with my quality consultant. I have other consultants for cell line development work and for helping design animal toxicology studies. I hope this doesn't offend anybody, but I only pay for them when I'm using them. Internally, we just keep things really, really small. You could say we are trying to get big by staying small."

CLOSING CURTAIN

Kaczmarek made some comments we can use for summing up. He said that supply chain management comes down to assessing your company's risk and tending relationships accordingly. "Up front in outsourcing, the technical piece is important, but you have to weigh the relationship with your company's risk profile. How much do you really need to invest in, and manage, each relationship?"

And my final aside: As Pryor knows, humor can deliver the clearest message. He's shown us that for this era of burgeoning biotechs, startups, and virtual companies, the "supply chain" is a strictly scaled and lean apparatus built piece by piece and impermanent. "Like many companies today," Pryor says, "we have a single product on a tight budget. I'm involved with everything, the glue that holds the activities together. I hope I avoid getting stuck." L

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A Process Validation – Of Self *And* Service

LOUIS GARGUILO Executive Editor, Outsourced Pharma @Louis_Garguilo

Our industry is science-driven and technical, and we are overall a society of specialists. No one can understand in detail all that makes up the development, manufacturing, and commercialization of a specific drug.

At the same time, possessing the inquisitive qualities of the scientist and engineer, most of us also have an interest, to the extent possible and time permitting, in learning more about segments outside our expertise. In a sense, this is a self-validation of who we are as individuals that collectively make up the pharmaceutical industry.

In terms of individual careers — and despite a continuing trend overall toward specialization — I'd suggest that those most inquisitive about both their internal and external realms climb the highest. When we do venture into the science and technology, business strategies, tactics, and various challenges beyond our expertise and throughout the industry, we often find similarities with our own fields.

One of these (rather amusing) similarities is that the "experts" aren't all that confident about the details of their own field. This can be experienced when wandering into another realm of validation, that of drug development processes, drug substance, and product. Here we encounter a field full of debate, some moving pieces, and comments such as, "It's up for interpretation." Perhaps the first thing we encounter is a realization that the FDA has simultaneously laid both a heavy and light hand on the shoulder of the validation professional. In other words, it's "follow the guidelines" but elucidate case-by-case. Let's try to validate how it's working out.

GUIDANCE FOR THE JOURNEY OF DISCOVERY

Even if we who know little about process and product validation, if put in a room with such experts, we'd expect to hear (mind-bending) quality statistics, experience table-thumping analytical fortitude, and see charts, graphs, and schema of exacting science and statement. And indeed often within their meetings, you do get all of that. But we'd also get an earful of comments like "It's up to interpretation," "That depends," and my favorite, "Do we need to follow the guidance?"

With no malicious intent — it all stems from a lack of knowledge on my part — but these experts of expected exactitude can sound more like weathermen predicting the veracity of the prevailing winds. The forecasts are currently centered around a piece of FDA advice entitled, "Guidance for Industry/ Process Validation: General Principles and Practices." Like the larger world of cGMP, documents drive discussion that leads to actual implementation. What adds to the "popularity" of this current document — first published in January 2011 — is the fact it's an updated version of the original guidance on the subject … issued in May of 1987. (For the record, I was still in Mt. Carmel Elementary School.)

The document states: "Since then [May 1987], we've obtained additional experience through our regulatory oversight that allows us to update our recommendations to industry on this topic." That's just shy of 30 years of accrued knowledge to update! Now multiply that by hundreds of drug manufacturers working with hundreds of CMOs to make sure we're all up to speed. Add that the guidance "aligns process validation activities with a product life cycle concept and with existing FDA guidance, including the FDA/International Conference on Harmonisation (ICH) guidances for industry, Q8(R2) Pharmaceutical Development, Q9 Quality Risk Management, and Q10 Pharmaceutical Quality System," and we've entered into an interesting warp of pharmaceutical space and time.

A VALID VALIDATION INTERPRETATION?

Continuing our "travel" into this new realm, we can capture (with validated equipment, of course) discussions such as these (which take place at locations such as Outsourced Pharma Conferences).

Q: *Interwoven within the guidelines from the FDA on process validation — now five years old — and the progression from Phase 1 to Phase 2 are concepts and approaches for technology transfer. How do these process validation guidelines apply and how often are they incorporated into a tech transfer to a CMO?*

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A: *It very much depends on who the customer is. If it's a virtual customer, with one person tasked with this activity, such as what I'm currently doing at my company, there aren't subject matter experts. You're relying on the CMO to be doing most of the work on implementing the proper validation protocols. For this type of sponsor, it helps substantially to maintain the same CMO, as long as they have a proven track record, when moving your compound from Phase 1 to 2, and even more so from Phase 2 to 3.*

> *"The FDA has simultaneously laid both a heavy and light hand on the shoulder of the validation professional."*

A: *Conversely, if you're a large pharma with strong technical support and subject matter experts, it'll probably work much differently. You'll be prescriptive about what you want and drive protocols. So from a validation perspective, there will be less of an issue if the decision is to change CMOs between stages.*

Q: *If I understand your answers correctly, it depends upon the customer and it depends upon the company size when deciding process validation. Is that to say that throughout the industry we're not uniformly implementing the FDA guidelines for validation?*

A: *Well, you could ask the same question about GMPs. There's not a checklist saying, "This is exactly what I need to do." It's following the intent of what's being asked for. You should be able to prove that intent to the FDA. For example, there are four or five different ways you could do a careful, low-risk and high-work maintenance validation, with strong documentation and an intensive experimental scale-down/scale-up process for a compound ... or you can do the bare minimum to conserve early funds as interpreted within FDA guidelines, as long as you are in discussions with the FDA as to what you are doing and your objectives.*

A: *If it's a product expected to progress very quickly, perhaps meeting unmet medical needs, from the side of the FDA, it would probably move faster through process validation than if it's a follow-on biologic. Although the standards for validation aren't relaxed by inspectors, the extent of testing and monitoring may be reduced. If a company has a fast track, and they're willing to take higher risk, they're probably going to minimize the work versus a company with a low-risk tolerance that needs everything to happen right the first time. Yes, to answer your question, there is a high level of variability on how process validation is done and can be approved by the regulatory bodies.*

A: *Agreed. You'll get six different answers, if you ask that question of six different people. Obviously we all know this, but particularly nowadays, you should start your interactions with the regulators as early as possible. Chances are they will have requested some additional characterization of your product and process at some stage during the development of your molecule anyway. And you definitely should have your CMOs involved in all of this.*

A: *I think many find that this type of coordination and interaction actually leads to* pleasant *surprises. There are some flexibilities that the agency will provide. They're not going to be very liberal, so to speak, but on some points, depending on the data that you have and can generate, you could propose certain strategies, which include a very high level of product characterization, to make the agency comfortable.*

A: *We just went through that. We were actually very happy in terms of the discussions we had with the regulators. We were trying to utilize two different sites as part of the commercialization process. One was at a CMO where we had done all the clinical fills, and then the other was an internal site for full commercialization production. The discussions with the agency on the strategies for validation actually ended up being very good.*

THE VALIDITY OF IT ALL

To bring us back from this journey of validation, and in case you are looking for some firmer ground to again stand on, we can end with a more direct interpretation of the state of this field.

A: *Validation guidances are near and dear to me. I practically sleep with this FDA document under my pillow. It's five years old now, and in many meetings and discussions with the FDA, I've learned the agency indeed takes it for granted that the industry has already fully adopted at least this new validation paradigm.*

A: *So much so, that a lot of the FDA's focus has already moved on to the quality metrics side of the equation. I've been in quite a few discussions with sponsors, CMOs, and the FDA, and the question often comes up, "Is this process validation really required or is this just a recommendation?"*

A: *Well, if you just read the opening pages of the new quality metrics draft guidance, the authors make it quite clear that they view the process validation paradigm as a* requirement. *It's an aspect of GMP. I've been surprised by what a strong stand they've taken. Frankly, I like seeing that. I think it makes good business sense that sponsors and CMOs look at it as more than just a compliance requirement. I do not think it's optional to adopt the new validation guidance.*

So there. Perhaps it is a more "settled science." Now it's back to the actual document for more interpretation. At least for some of us. Best wishes.

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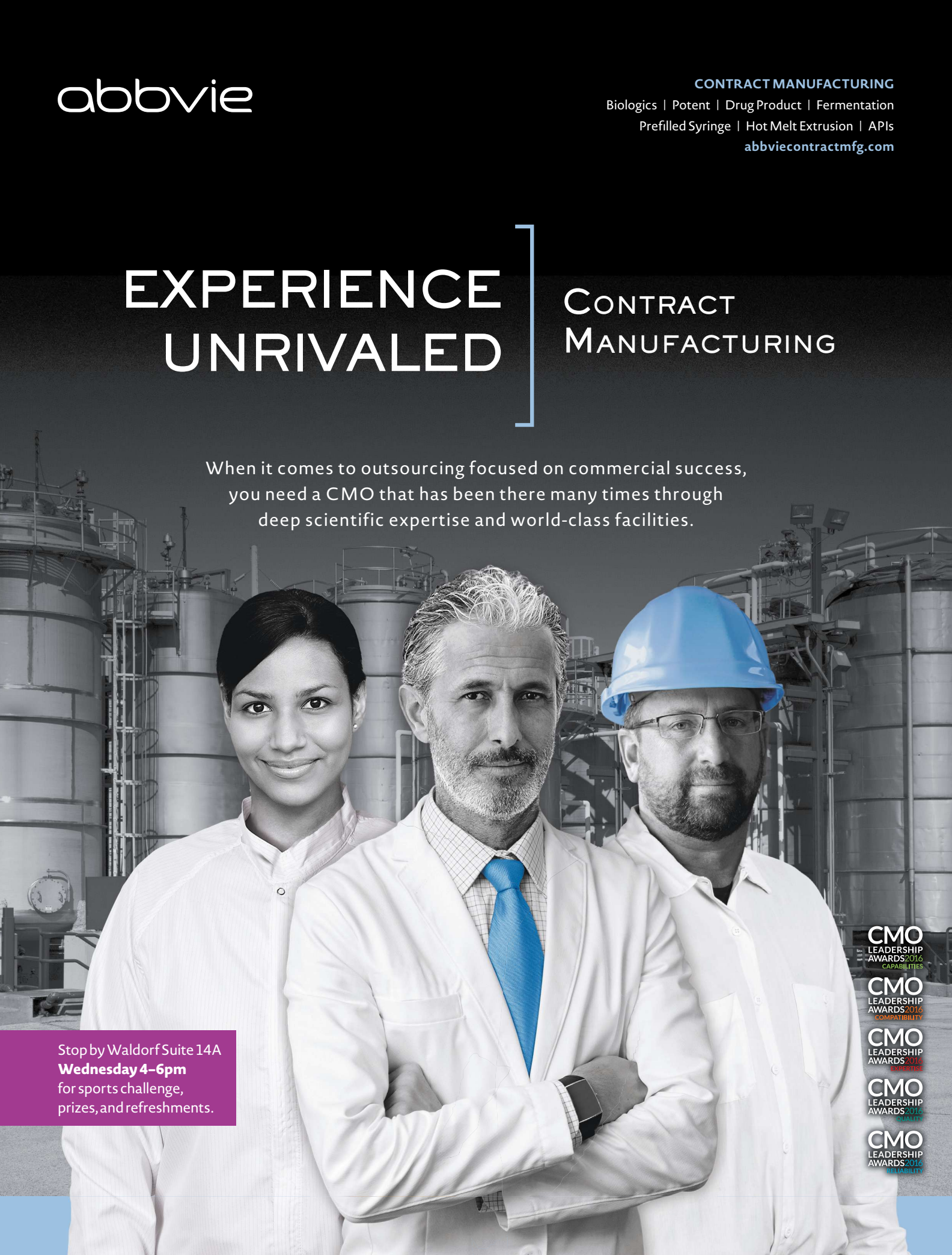

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Who's Got The Best Tech Transfer Protocols?

LOUIS GARGUILO Executive Editor, Outsourced Pharma @Louis_Garguilo

An exasperated pharma veteran publically voiced a widely shared concern via an open question: "Our industry's been engaged in tech transfer for some 30 years, so why haven't we gotten really good at it?"

"It does make me wonder," replied a second industry executive at the same forum. "I've seen tech transfer at Big Pharma continue to pose problems through this decade, including between internal sites. It remains a challenge."

That ongoing challenge has increasingly led to another question, this one posed in more hushed tones (and some conspiratorial drama): "Do you think the CMOs have developed strategies for tech transfer that may be superior to pharma's own?"

Here's what some professionals have to say.

EXPERIENCE TRANSFERS WELL

"One of my first projects years ago was perceived as a straightforward commercial tech transfer from a customer," recalls Siddharth J. Advant, president — Biologics, Kemwell Biopharma. "We thought, 'It's a set commercial product, so what's the big deal?' But as many now know, when you have to fit a process into a new facility, not everything performed in the original location is going to work in the next one. I've learned it's not a matter of who has the best tech transfer strategies but, more importantly, who has the most experience."

Besides his general tenet regarding the primacy of experience, Advant suggests a specific approach to more effectively transfer product into any facility: Scale-down models should be performed to gain a deeper understanding of challenges before proceeding to the desired scale up within the CMO's manufacturing format. "Of course the client has to agree to the strategy, and be a willing partner in these activities," says Advant.

That final comment on client acceptance can be the most difficult part of the equation, according to so many I've talked to over the years at CMOs and from some personal experience. It's the sponsor's project. They are paying, and they often feel they know what's best in the transfer process. Advant says that to help gain acceptance — or recognition of experience and knowledge of at least one's own facilities and equipment — his company shares a "guidance policy" with clients. He says that when CMOs clearly detail the aspects and their methodology of tech transfers at the different stages, it helps ensure both sides understand the experiences of the other and also helps in setting realistic goals.

"It's not that we have to do everything our way or even a certain way," concludes Advant. "But at the end of the day, the CMO is expected to deliver to the customer. And that starts right off the bat with the project transfer working out."

SIZING UP YOUR PARTNER

Hank Stern, VP CMC, Alexo Therapeutics, says it's difficult to determine whether one organization does tech transfer better than another. However, he lets us in on some telling research regarding the potential costs of a commercial-scale project, which may help inform a sponsor on technology-transfer discussions and decisions.

Stern puts that in perspective. "If you ever went to a CEO at a smaller pharma company and said, 'We need 40 FTEs to do a tech transfer,' it's just not going to happen. All sponsors, particularly smaller pharma or virtual companies, need to ask: 'How do I fully leverage the systems and processes at my CMO?' You may feel like you lose some control, but you can effectively minimize resources and gain the full experience of your partner manufacturer." The key here, of course, is to make sure sponsors have

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selected the CMO with the right experience for their projects.

Ulrich Ernst, SVP Manufacturing & Quality Operations, Amunix Operating, Inc., agrees the methodology and best practices selected for a tech transfer depend on the partners involved. He's arrived at his views from the perspectives of someone who has worked at large and small pharma, and as a contract manufacturer. Here are his three "points of attention" for both partnering organizations:

"First is the overall scope of the project the client is bringing in. By that I mean it's important for both sides to ensure there's proper communication on the intent, scale, specific needs, timing, and quantities to be delivered, and all the expectations around those parameters. Scale is important both on an operating level and in terms of the technical requirements at that level. You're building a lot of detail into a mutual plan for success.

"Next, you need to explore and understand strengths and weaknesses on both sides. A large partner on either side may bring a lot to the table, but a smaller one can bring certain pieces as well. If any of the pieces, such as process development, project and facilities management, or quality requirements, differ from the partner's expectations, you'll run into problems at some point.

"Finally, understand the structures that need to be in place around the project, including starting with doing a business development plan. You need agreements that ensure alignment from business, legal, technical, and quality standpoints. Ensure you understand the obligations of both partners. The best tech transfer strategy is the one where both sides are completely on the same page."

THIRD-PARTY CRASHING

Getting on that same page may require another pair of hands. Assisting with tech transfer is one of the most important roles consultants and other trusted partners play in the client-provider relationship.

For example, there are times when sponsors have been working with a CRO or CMO because of recognized expertise or relationships earlier in the life of the project. The sponsor, though, may become less certain of the CMO's prowess for the next phase. Both Stern and Ulrich agree if you don't feel comfortable — or have the sense that either you or your partner does not have the capability — you should consider finding a third-party source to help you, whether that's a consultant or another partner company.

Of course bringing in a third party to help you understand or execute on a critical tech transfer can also add an additional layer of complexity. However, according to Ulrich, what nobody wants is to "have to do it twice, because of some failure the first time." Despite the pressures, he says, there's usually more time that first time, and it gets more expensive with any failures. "Smaller sponsors also understand well the financial pressures and the cost rationalization that's going on in the industry today. The expectation is, if you don't know something, you should know somebody who does, and you should bring them on board to help sooner rather than later."

What sponsors may find after conferring with consultants is that a solid dose of introspection is in order and, perhaps, so is a renewed commitment to the same partner. Stern suggests if you're a small company contracting a CMO, and it's not quite working out, perhaps from a new technology-transfer perspective, you probably do want to see if you can work through it. He puts it this way:

> *"It's important for both sides to ensure there's proper communication on the intent, scale, specific needs, timing, and quantities to be delivered, and all the expectations around those parameters."*
>
> **ULRICH ERNST**
> SVP Manufacturing & Quality Operations, Amunix Operating, Inc.

> *"I've learned it's not a matter of who has the best tech transfer strategies but, more importantly, who has the most experience."*
>
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> *"All sponsors, particularly smaller pharma or virtual companies, need to ask: 'How do I fully leverage the systems and processes at my CMO?'"*
>
> **HANK STERN**
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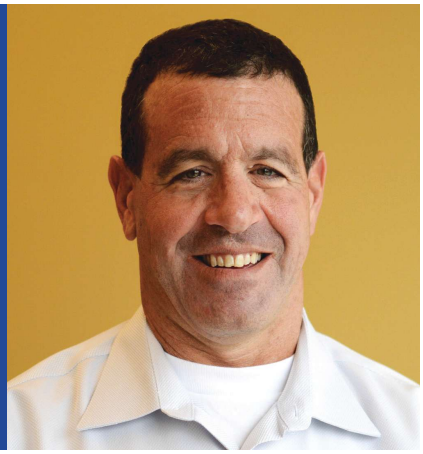

"You treat the CMO as one of your employees. If your employee is not working out, you want to make sure you've provided clear direction. What part of ownership are you taking for any problem or uncertainty in capability? Have you provided sufficient resources and information? Have you communicated closely and provided feedback? Are you willing to invest in your partner to add capacity or ensure capabilities? You should be saying, 'Hey, here's where it's not working out. Can you change staff or equipment? Can you change the way you'll process this?'

"However," he continues, "just like that employee who's not working out, you're not going to spend forever figuring things out. At some point and in some cases, you have to say, 'Look, this is not a good relationship for either of us.' Often it's also better for the CMO to move on."

A final word from Kemwell's Advant: "If you've had the right discussions throughout the relationship, both sides will already know clearly and be prepared for what is coming next. Again, the best transfer techniques and decisions are always a result of mutual understanding."

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5 Comments On Choosing A Global CMO

LOUIS GARGUILO Executive Editor, Outsourced Pharma @Louis_Garguilo

I'm amazed that today's biotechs and drug developers are still questioning whether they should search globally for a CMO. But, since this is a difficult business decision for many companies, I decided to compile the following (edited) excerpts from a panel discussion at last year's Outsourced Pharma West conference in San Diego, which I believe could help.

The panel was moderated by **Jeff Barker**, principal consultant and sr. advisor, Rondaxe. The panelists were **David Enloe**, president/CEO, Althea; **John Gregg**, president/CEO, BalinBac Therapeutics; **Brian Mendelsohn**, leader of ADC Chemistry Group, Agensys; **Nils Olsson**, VP chemistry, manufacturing and controls, Retrophin; and **Nicholas Virca**, president/CEO, HedgePath Pharmaceuticals, Inc.

Looking Globally For CMO Support Is Inevitable

First, approach outsourcing from the realization you cannot know everything. But what you can do is find some experts in the areas most vital to your project or business model. That was especially important when I joined my company because we are not married to any specific technology or disease but more driven by business development opportunities in general.

It was clear to me from the beginning that I couldn't handle our CMO search or management of outsourcing alone. Therefore, my initial objective — over the first year or so — was to bring in a small group of experts that I could fully rely on and that did not require any hand-holding. I was fortunate to be able to bring good people on board. Experts like this are out there for you, too.

And it's no coincidence that the individuals I selected for our internal group came from the four corners of the world. They knew all the key service providers in their fields. So we felt no limitations about where to go in our search for CMOs. We now work with CMOs here in the U.S., in Europe, and Asia. In my opinion, looking globally for the best fit seems inevitable nowadays, and there are strategies to do so.

Balance Your Risk/Reward

I think the answer to every question regarding global outsourcing is, "It depends." There's so much risk that a company takes on with the "four-corners-of-the-world" approach, particularly depending on what your specific product is and what it requires.

For example, with a biologic where the process might not be fully tried and true, yet there's a lot of expertise and knowledge that resides with the sponsor. It will require a ton of interaction and knowledge transfer to a CMO, and you'll be trying to have that across multiple time differences — and perhaps at times some language differences — if your provider is in a far off location. Small inaccuracies — a subtle miss — can lead to a failed batch in an early-stage process. It can bring a project to its knees.

I think sponsors need to be balanced regarding risk/reward when considering local vs. global outsourcing. Frankly, I'm always astonished at how many people say how far and wide they looked, and then how glad they are not to have gone so far and wide.

Always Be Looking For Partners

Maybe our company takes a slightly different view of this. We don't really ever start looking for CRO or CMO partners for different projects; we're basically always searching globally. Perhaps that's a luxury we have because of a constant need to find partners and because we have the headcount to do this kind of networking. But we're always talking to people, we're always looking, and we do it in Asia, North America, and Europe.

We find that the global search really increases our ability to find the best and most appropriate partners for the kind of work we need done. We look at every aspect of the CRO and CMO we think is important to accomplish our due diligence. For example, our quality team attends technical audits with us to review quality systems. All of this has become just the normal way we go about outsourcing ... and doing business.

It's A Big Adventure With Potentially Big Cost Savings

COMMENT 4

You'll learn that in this industry there's not one partner who can magically do everything you need. You'll most likely have to mix and match, and you'll have to learn to balance time to manage these CRO and CMO relationships. In the beginning, this really was a struggle for me.

However, I'm convinced the extra upfront work to find the right partner and do that extra management has paid off. We feel we got the CRO that could do our formulation best and the CMO that could manufacture most reliably for us.

To be clear, though, even going to India or China for starting materials can be a big adventure. But it's a big adventure for potentially big cost savings. You simply have to do your due diligence. At times we hire reputable brokers for some locations. That's one way to get started and bring international service providers on board. Brokers or agents, though, can't replace your own due diligence. You have to visit the CMOs and kick the tires, particularly in China and India.

So it is a healthy exercise first to think through whether you even want to pursue global opportunities. In the end, I agree a lot depends on your development plan for your product and overall goals for your company.

It Takes Effort To Stay Connected — But It Can Work

COMMENT 5

We try to be as interactive as humanly possible from the investigative stage through any relationship we establish with CMOs. So, generally speaking, you can say it is a benefit to have a CMO close to your geographic location. You can easily meet people face-to-face and go out and look at samples and processes when you like.

Nonetheless, in these times of various global and instant modes of communication, you can also interact quite easily with people anywhere in the world. If you take advantage of this and make the extra efforts to stay connected, you can make it work.

Particularly, if you are going to search globally, the key is to establish more than communication, but a good working relationship with CMOs from the initial selection process. A fundamental question — no matter where in the world they are located — is do they have a group of individuals at the service provider that your internal resources can easily communicate and get along with? Frankly, you should consider whether they are fun to work with. If it is going to be a struggle, why bother?

Ah, To Be A Project Manager In 2016!

LOUIS GARGUILO Executive Editor, Outsourced Pharma @Louis_Garguilo

This is the reality that 2016 has wrought: Big Pharma is continuing to organize for enhanced utilization of external partners and supply chains. More business models — biotechs, startups, virtuals – rely on outsourcing. CROs/CMOs are reacting to these client changes with their new service models, technologies and facilities, and M&As.

Add the fact of more but smaller projects at a quickened pace of delivery and turnover, and it all leads to, among other things, a weight and force landing on the backs of a particular set of individuals:

Ah, to be a project manager in the biopharma industry in 2016!

Are "PMs," as they practice their trade today, up to the new challenges and intensifying outsourcing landscape?

WHO'S A PROJECT MANAGER ANYWAY?

"When we talk about managing projects in our industry," says Heidi Hoffmann, senior director for manufacturing at Sutro BioPharma, "we're often talking about it generically, in terms of how do we ensure both customer and supplier get what they need for a specific project, considering the time and money available and the activities that have to be done? But who is tasked with doing this on each side — sponsor and their service provider — varies with project and organization size."

Hoffmann comes at this discussion with over 20 years of experience, including working on vaccines for influenza (FluMist) and plasmid DNA for gene therapy. She was also part of the team involved in the transfer of Bristol-Meyer Squibb's Orencia (abatacept) production to a CMO facility in South Korea. Perhaps somewhat surprisingly at first, she suggests that in today's fast-paced drug-development environment, small sponsors, and at times Big Pharma, may not actually need what might be considered "professional" project managers to succeed. The real requirement, she says, is simply ensuring you have someone authorized to make day-to-day decisions who can communicate effectively and directly with the CMO and is capable of weighing overall risks and tradeoffs as projects progress.

Sounds simple enough. No specific project management background, such as a Master of Project Management from Penn State or other universities, is needed. This opinion is bolstered by various conversations over the last two years with representatives from Big Pharma, biotechs, CMOs, and consultants. No one denies that a well-defined or pronounced subset of "professional PMs" exists in our industry. When asked how companies recruit or acquire project managers, the most often reply is the roles are filled internally with scientists (or engineers) who get "promoted." These people climb the corporate ladder by successively managing a small team, an internal project, projects relying to a high degree on external partners, and culminating in alliance or relationship management positions. A PM in our industry is a scientist or engineer who's the product of an incremental increase in responsibilities and on-the-job (OTJ) training.

There's certainly nothing wrong with OTJ. But it serves us well to note carefully this means the project managers at sponsors today are experiential products of the way projects have been managed in the past. On the service provider's side as well, it's common to find PMs who are former pharma project managers. Can these individuals on either side evolve their roles to meet the trends in the industry? Or, if we understand Hoffmann and many others, is there actually less need of an evolution in the PM role than we might have anticipated? (Count me as an early member of this anticipatory group.) Instead, we see the industry further embracing the traditional role

and selection of project managers: We're not clamoring for new kinds of PMs; we just need more of what we have, we seem to be saying.

"For a well-defined and understood project a CMO has done before or involves a routine or proven platform," Hoffmann explains, "a 'regular' project manager does a great job of keeping track of tasks and resourcing appropriately, while also keeping communication lines open when things aren't going according to plan.

"For a new project or something that's more outside of the normal paradigm, I find it works best to consider the role of a *project team leader* more than a *project manager*. These managers have a solid grasp of the science related to their project. They're not as subject to, let's say, manipulation by the external partner. I've found that 'professional' project managers, often with less science background, don't know when to say, 'Wait a minute, that doesn't sound right. I'd better check on that.'"

THE ELUSIVE PM UNICORN

Hoffmann's points may sound familiar to readers, and her thoughts lead us back to the well-worn discussion of the ideal makeup of the individual project manager. Like some Socratic dialogue, the discussion turns on a fundamental question: "Should PMs be more technical or business savvy, more scientist or manager?" Although Socrates might not have approved, a lot of us are prone to answer, "Yes to all the above." Unfortunately, while that ideal sounds good in discourse, in reality this superior being is in fact still unicorn rare.

Since these advanced scientists-project managers are hard to come by, we expect the industry will focus on structured training and development of PMs within the current promotional system. If there are formal and rigorous programs at sponsors and service providers, it seems they are being kept secret.

Joe Guiles, head of development at Agilent Technologies' Nucleic Acid Solutions Division, has heard this scientist-project manager dialogue before. Guiles, like Hoffmann, is a 20-plus-year veteran of the biopharma industry, including positions at biotech Medivation, service-provider Cedarburg Hauser, and

pharmaceutical companies Sanofi-Aventis and Johnson & Johnson.

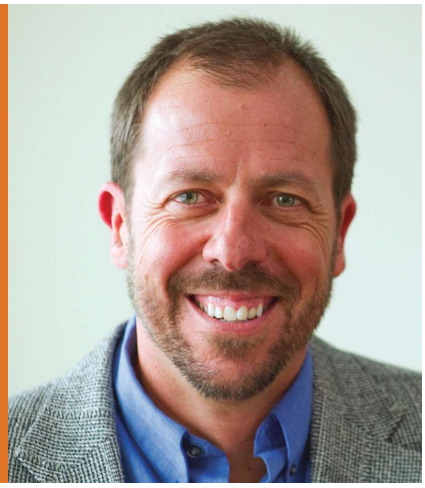
"We have project managers at Agilent serving in that role of scientist-manager for several of our clients," he says. "We use them as an important *tactical* window, meaning that they are on the front lines, and their reporting flows up to a more senior management level. These front-line managers say things such as, 'Here's what we're seeing, what's working, and what's not working.' They are the ones actually interacting with the CMO and know whether the relationship within their individual project is going well. But their role more or less starts and ends there. These PMs need to be able to solve many of the day-to-day challenges themselves."

The more senior management stratum Guiles just mentioned is, of course, the "Alliance Management" function and/or steering committees, often set up by larger sponsors like an Agilent or pharma company. "This next level up is the venue for the more strategic discussions," notes Guiles, who then adds: "A pet peeve of mine is when these strategic discussions are not productive because we get bogged down in tactical PM dialogue."

Unfortunately, we won't be able to dive into this second level of project, relationship, or alliance management in today's investigation. The point here is that both Guiles and Hoffmann, as well as so many others in the industry, agree (or simply don't challenge) the fundamental role and type of individual still needed as project manager in today's outsourcing (or internally, for that matter) hasn't really changed. These managers are the scientific versions of the factory-floor foremen, advanced tacticians able to keep people, equipment, and schedules humming ... and with the knowledge to hit the reset or stop button when necessary.

Ultimately, today's increased outsourcing, complex projects, new business models, advanced technologies and platforms, and faster timelines, all seem to add up to a simple need for more project managers in their current shape and form. While this has been a limited thought experiment, we *have* been able to demonstrate an industry mostly satisfied with the current roles of its project managers. I, for one, sit surprised at this result. Or perhaps we've missed something here. Maybe some readers have more to add. Please let us know. In the meantime, I'll let you know we will further pursue this topic of project management at *OutsourcedPharma.com*, as well as in *Life Science Leader* magazine.

> *"A pet peeve of mine is when ... strategic discussions are not productive because we get bogged down in tactical PM dialogue."*
>
> **JOE GUILES**
> Head of development, Agilent Technologies' Nucleic Acid Solutions Division



> *"I've found that 'professional' project managers, often with less science background, don't know when to say, 'Wait a minute, that doesn't sound right. I'd better check on that.'"*
>
> **HEIDI HOFFMANN**
> Senior Director for Manufacturing, Sutro BioPharma

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Don't Overlook Intangible Metrics When Evaluating A CMO

LOUIS GARGUILO Executive Editor, Outsourced Pharma @Louis_Garguilo

Something Denise McDade of Capricor Therapeutics said during a session at Outsourced Pharma West in San Diego last year stuck in my mind: "Metrics are fundamentally important in measuring and managing any relationship, but there's a paradox when it comes to outsourcing."

That paradox stems from an awareness that while there is a rising criticality to establishing a tangible set of metrics for your outsourcing partners, those increasingly important metrics still don't offer as complete a picture as many would believe. Even with more sophisticated performance measurements for items like cycle time, throughput, deviations per batch, time to resolve deviations, on-time delivery, surpassing quality or quantity goals ... these results may lead a sponsor astray at times.

According to McDade, VP of quality, and whose career has spanned various positions at Genentech, Novartis, Amgen, and other biopharmas before joining Capricor, there are equally critical elements — such as trust and the spirit of the supplier relationship — that defy even today's finer metrics. Here's a closer look at what McDade and others are saying.

> *"On paper, performance can look similar, but from a relationship standpoint, performance can turn out to be completely different."*
>
> **DENISE McDADE**
> VP of Quality, Capricor Therapeutics

DO YOU KNOW YOUR CMO EVEN IF YOU MEASURE?

McDade made her initial comments as a panelist at on OPW session titled, "How do you know you're on target if you don't measure your CRO/CMO?" Other panelists included Michele Johnson, director, supplier relationship management, Sandoz; Sylvie Sakata, sr. director, external research solutions west, Pfizer; and Nicholas Virca, president & CEO, HedgePath Pharmaceuticals, Inc. John Newsam, CEO, Tioga Research, was the moderator.

No panelist or member of the audience was advocating less measurement of CMOs. The pendulum has certainly swung to the side of "the more measurement, the merrier," away from a substantially less vigorous approach of even a few years ago. A separate panel at OPW dealt specifically with new FDA statements exploring the need to measure "culture" as a function of reliably deriving a quality product. This panel also included discussion on the FDA's plan to receive quality data directly from CMOs.

But back to McDade. She has arrived at her convictions during a career that spans more than 25 years. During about half that time she has been focused on the outsourced world, while the other half she has been on the manufacturing owner-operator side.

"I've worked with CMOs where we had a robust and healthy management process, ample performance feedback, and a lot of measurement," she explains. "However, there was still little trust in the supplier relationships. Ultimately, those types of relationships were not successful or healthy in an overall business sense. It's difficult to measure exactly what the issue was with trust, but it was crucially important for the CMOs to try to maintain — or salvage — it as a part of their relationship management efforts with us. Therefore, I've seen that both sides — the measurable and the more intangible components — are equally important. In my experience, you can't be successful unless you have both."

THE 5 A.M. CALL BUILDS TRUST

At the conference, and in a follow-up discussion, McDade walked me through an example that draws out her feelings.

At one point in her career, she was outsourcing the same product to a CMO in the U.K. and one in the U.S. There were similar quality agreements in place stipulating that within 24 or 48 hours the CMOs inform McDade, as head of quality, of different levels of deviation that might occur at the facilities during the manufacture of the products. "The U.K.-based CMO had a facility contamination issue in an area of their facility that ultimately didn't impact our product," McDade explains. "However, I got a call at 5 a.m. my time from their QP [Qualified Person, as referred to in Europe] so I could be informed as soon as they found out. There were other times as well where the QP would pick up the phone to let me know immediately of anything that he thought I should know."

There was also an issue at the U.S.-based CMO, this time a critical contamination in

its WIFI (purified water) system. Again, the issue was not occurring in McDade's part of the facility, so by a strict reading of the quality agreement the CMO was not obligated to inform McDade's company. In fact, McDade only found out about the problem after the CMO was inspected by the FDA and received a warning letter.

"By strict measurement, both CMOs were within the language of the contract, but only one was within the spirit of the relationship. Which one did I trust and continue to work with? You could look at the numbers on the metrics reports and they might be similar, but the quality of the relationships was totally different," she explains.

CAN YOU METRICIZE TRUST?

The OPW panel agreed that the trust factor would not diminish in importance because more and better metrics are put in place at the sponsor to measure provider performance. In fact, the same reason for an increased need for CMO metrics also bolsters the need to have the intangibles — like personal relationships — contributing positively to outsourcing outcomes. As one panelist said, "You can't have a relationship with an organization; you have a relationship with individuals." While systems and processes are set up so that projects, processes, and relationships are not "completely person-dependent," sponsors will always be "somewhat dependent upon the individuals on the other end."

It's important to have an open structure where the letter and spirit of the relationship can be transitioned as personnel changes — at either the sponsor or provider. One panelist talked about working with a supplier who had to replace project leaders a few times, but "how the transition was accomplished had a huge impact on how successful and seamless we continued to move forward." Trust as an independent variable gets high marks for how well productivity, quality, and reliability — and the relationship itself — are sustained over time and as people change. That trust then becomes the yardstick for the entire organization as a fully reliable partner.

McDade has had outsourced supply chains find ways to document intangibles to head off any paradox cropping up in the more standard metrics. These broader measurements became an important part of an overall supplier scorecard.

"We measured items that were subjective by applying a numeric rating to them and then presenting these ratings as parts of our quarterly review meetings with the supplier. We actually spent a fair amount of time talking about these items with our CMOs so they understood the importance to us," says McDade. She adds: "We measure and measure. On paper, performance can look similar, but from a relationship standpoint, performance can turn out to be completely different. For me there is always another equally important ingredient in that relationship, and that is trust."

CMOs And Pharma Sponsors: Who's The Rhino And Who's The Tickbird?

SUE WOLLOWITZ President, Wollowitz Associates LLC

The rhinoceros and the tickbird have a symbiotic relationship. The tickbird eats insects off the rhino, providing food for himself and insect control for his or her host. But would you say that the tickbird and rhino have the same needs and wants? Does the rhino want a nest on his or her back, and does the tickbird want to go swimming?

Biotechnology and pharmaceutical sponsors and outsourcing service providers are in the same type of relationship, if not on the same savannah. The relationship is symbiotic — to a far greater extent than a mere mouthful of insects. But the fact is the sponsor and the service provider also want and need different things from the relationship. They agree on what a sponsor wants from a service provider, but what the service provider wants for itself is a rarer focus of discussion. Let's start from the side less discussed.

CMO NEEDS SPOKEN ALOUD

Mid-last year, I read an interview with Samsung BioLogics' President and CEO, Tae Han Kim, at OutsourcedPharma.com. Kim took the unusual step of talking about what a CMO business needs, from a business perspective, to be world class. "I define the CMO champion as having the largest, top-quality manufacturing capacity, the largest revenue, and the greatest profit," Kim said. While some might disagree with his comments, they were honest: For a CMO business to be viable, it needs to operate at high capacity, it needs reasonable operating margins, it wants return customers so there is less marketing spend required, and preferably long-term agreements with sponsors to stabilize finances. But does a sponsor select a CMO because it has the largest revenue and the greatest profit margins? Probably as much as a CMO would provide quotations only to those sponsors with the largest sales volume.

What sponsors want out of CMOs — *should* want out of CMOs, or how they should rate CMOs — is the subject of an article once per month in some periodical or in some blog, authored by people on both sides of the fence. Are CEO Kim's the universal traits that make a CMO "world class"?

TRACEABLE TRAITS

In my experience, what becomes important in an outsourcing relationship is how to ensure the two parties effectively contribute to the business goals of each company. This is easy when the goals are aligned, but often they are not, and it becomes more challenging if the parties' measures of success for even the same activities differ. While on-time batch release or a successful FDA audit may represent shared business goals, there are surrounding and various other activities that require compromise to get to business successes for both parties.

Two of the most challenging areas are in production scheduling and managing scope changes. While both parties want on-time delivery of ordered goods, the desirable delivery schedules are not always aligned. Sponsors are frustrated by long lead times and elongated production schedules, by back orders on raw material inventory, and a seemingly

inability of CMOs to be more flexible and accommodate schedule change requests. For example, the inability to obtain material on time may be costing the sponsor in lost revenue, in extra costs for back-up options, or in marketing losses even before production starts. On the other side, the production facility tries to schedule six months to a year out so that it can more efficiently plan personnel and equipment needs to lower its costs and raise operating margins. To accommodate the sponsors' schedule changes for whatever reasons, CMOs have to maintain idle capacity, perhaps expand to a seven-day week to then shorten a production run, take on the expense of storing larger inventories of raw materials, and mess up the queue for analytical work.

Moreover, where production is all about scheduling, development projects are more about scope and flexibility. Sponsors need flexibility to make scope changes in requested project activities as data is obtained and analyzed. Results obtained in the sponsors' facilities or the CMOs can narrow, expand, or refocus the subsequent activities required to move the project along. Results from safety, pharmacology, clinical trials, or marketing assessments can impact the scope of activities at the CMO. Flexibility may also mean speed of progress needed, changes in batch sizes, amount of testing required, etc. It may mean changes in process or formulation definitions that call for less frequently used equipment, and at a variety of operating scales, e.g., for isolation and drying, purification, granulation, or testing. Oh, and of course, through it all the sponsors will demand their project remains prioritized over competing activities at the CMO.

"What becomes important in an outsourcing relationship is how to ensure the two parties effectively contribute to the business goals of each company."

SPOILED OR SUCCESSFUL BEHAVIOR?

Having been on the side of the sponsor, I know that all the above are not necessarily

evidence of spoiled behavior. Rather, the behaviors and requests are the result of the real-world timeline pressures that require making decisions — and often providing project guidance — with less information than desirable. It is a constant struggle to identify what needs to be evaluated in the current phase of activity and what could drag the project out. With breakthrough designations and fast-track status trending in the pharma business today, flexibility and responsiveness on the part of the CMO are even more important for the sponsor to achieve its business needs.

This is understood by the CMO, but this flexibility comes with costs to them, as mentioned above. What are the CMO's needs then? It starts with an understanding by sponsors this will mean more personnel time in managing increased internal and intercompany communications, scope changes, and scheduling regardless of whether it results in the CMO asking for additional fees or not. To provide this additional manufacturing responsiveness, it also means the CMO has to somehow maintain an even more flexible or open (idle) capacity in both labs and production areas. Interestingly, it is the CMOs that operate at very high capacity with great efficiency of personnel and equipment (i.e., the most successful CMOs) that might be less responsive to the customer who is dealing with uncertainties and incomplete knowledge on their own end. All of this harkens back to all of those articles we mentioned dealing with the subject of "what the customer wants"! There is still a lot to uncover in getting to a fully mutual sponsor-provider relationship.

Finally, let's all face it, our business is cyclic. Supply and demand says that the service providers will spend a lot more time worrying about accommodating the customer in dry years, but less in "wet" years. The most recent era of a favorable economy, and such things as new therapeutic technologies, may be providing the CMOs with more work and filled capacity, but at the same time take away from the ability to add this layer of flexibility sponsors now need. But as with the rhino and the tickbird, living in the same environment but having very different needs for survival, sponsors and providers rely on each other to thrive. And by the way, are we sure which is the rhino and which the tickbird? L

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The Value Of Experiential Data In Making Informed CMO Selection Decisions

As part of Life Science Leader's commitment to bringing the most valuable decision-making tools to its readership, the methodology and research supplier for the Leadership Awards has changed. Industry Standard Research, a full-service market research provider to the pharma and pharma services industries, collected experiential data on Sponsor-CMO service encounters that have transpired in the past 18 months to serve as the foundation for the 2016 CMO Leadership Awards.

KATE HAMMEKE
Market Research Director
Industry Standard Research

This approach, which provided feedback from recent customers across 26 performance metrics on more than 80 CMOs, more closely corresponds with the level of qualification important to the CMOs receiving the awards and the Sponsors that engage contract manufacturing services.

There are five core CMO Leadership Award categories: Quality, Reliability, Capabilities, Expertise, and Compatibility. Several performance metrics factor into each award category in order to help both Sponsors and CMOs to understand a quantified evaluation and accurately assess a supplier's skills within a category that can span a range of definitions. Have you ever asked your customers or vendors how they define quality? ISR has. And it's tricky to find coherent through lines (i.e., ongoing themes).

The change from perception-based data to experiential data is important because it shifts the focus of the awards from a CMO's reputation — a product of marketing, public relations spin, and any "industry buzz" about a company known by professionals in the industry — to how a CMO has performed for its current and recent customers relative to their expectations. How well a CMO executed its contracted responsibilities for customers is valuable information when it comes to making informed CMO selection decisions, particularly because industry perceptions don't always match reality.

This can be especially true when it comes to identifying industry leaders. ISR's CMO benchmarking surveys ask respondents to list up to three CMOs they think of as leaders in either small molecule, biologic, or drug product manufacturing services. This is an unprompted question where respondents are not provided with a list of CMOs from which to choose. As a result, sometimes a CMO was listed as a perceived leader for services the business does not offer — this can mean that the company is benefitting from the halo effect, a cognitive bias where an observer's overall impression of a company influences the observer's thoughts about the company's properties. But the halo effect is not always beneficial. When it backfires (so to speak), it can influence an individual to hold a company to higher expectations than warranted or expect a range of services and support in which the supplier has no expertise.

The data shows the 185 different suppliers were proffered by respondents when asked to name leaders in contract manufacturing. The three businesses receiving the highest number of mentions also are three of the largest CMOs and the CMOs that topped the list for proposal volume. In fact, CMO size (and the well-funded marketing budget that often accompanies size) appears to have a greater influence on perceived leadership than anything else, including how a CMO performed according to its customers. Alas, it's no surprise that customer experience can be drowned out by the marketing and PR machines; that is the purpose, after all.

But are the marketing communications designed to influence perception potentially harming the business by fueling high expectations? The in-depth results from ISR's research point toward a challenge of scale faced by service providers and vendors from all types of industries — service excellence can be diluted by large customer bases. Or, it's impossible to please everyone all the time. This impossibility is further supported by the absence of a consensus on the "most important attribute" for a CMO to possess — even for a particular type of project.

In addition to asking research participants to evaluate each CMO that they have recently done business with, the survey asks respondents to prioritize

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Figure 1

AWARD CATEGORY: QUALITY	RELIABILITY	CAPABILITIES	EXPERTISE	COMPATIBILITY	PERFORMANCE METRICS	PRIORITY: TOP 5	MOST IMPORTANT
●			●		Strong regulatory track record	40%	14%
●					Track record for meeting quality performance metrics	27%	10%
		●			Proven ability to manufacture API/dosage forms we require	27%	10%
	●				Reliable on-time delivery	41%	9%
	●	●			Has capacity to meet our demands	36%	6%
			●		Ability to smoothly scale up manufacturing and transfer technology	23%	6%
					Low cost	32%	5%
			●		Scientific knowledge	30%	5%
			●		Experience level of staff	29%	3%
●					Right first-time measurements	14%	3%
		●	●		Offers innovative solutions	9%	3%
				●	Well-regarded within the industry	17%	2%
		●			Facility has most up-to-date manufacturing technologies	17%	2%
	●				Flexibility to adjust schedule for special requests	14%	2%
	●				Metrics for meeting overall project timelines	12%	2%
●	●				Up-front contingency planning, risk management	10%	2%
		●			Stability testing capabilities	10%	2%
	●			●	Timely project communications	17%	1%
	●			●	Financial strength/ stability	17%	1%
				●	Access to desired markets	6%	1%
	●	●			All facilities fully owned (i.e., not subcontracted)	6%	1%
		●		●	Complementary core competencies to in-house or other manufacturing contractors	6%	1%
		●	●		Provides regulatory support for filing	11%	1%
				●	Cultural fit	10%	0%
		●			Storage capabilities	7%	0%
				●	Accessible senior management	5%	0%

the 26 performance metrics as "Top 5" and the "Most Important" when it comes to selecting a CMO. The metric deemed most important — strong regulatory track record — by the largest percentage of respondents, only captured 14 percent of the vote; 40 percent of respondents included this metric in the Top 5. A track record of meeting quality performance metrics and a proven ability to manufacture API tied for second position, with 10 percent of respondents stating one of these metrics is the most important attribute. Yet only one-quarter of respondents included these metrics in their Top 5, suggesting that these particular metrics carry significant weight to a fraction of buyers of outsourced services, but are less significant in CMO selection among a larger portion of the outsourcing audience. Reliable on-time delivery was the only other metric to be deemed the most important criterion by roughly one in 10 respondents (and among the Top 5 of 41 percent of respondents). Then, there is a steep drop-off in agreement on the most important selection attribute, and the next five metrics are each considered the most important to one in 20 respondents.

Some of the challenges of making an informed CMO selection decision can be alleviated by knowing which CMO performance metrics have positively contributed to successful outsourcing relationships among peers and then which CMOs have performed best on these metrics for their customers. The data in Figure 1 displays how the performance metrics are ranked by buyers of outsourced services and which award categories correspond to the performance metric. This data can be coupled with the 2016 CMO Leadership Awards winners list to help identify best matching CMOs for upcoming outsourced work. A mix of contract manufacturers with respect to both size/capacity and scope of offering won CMO Leadership Awards in 2016 based on how well these businesses performed for real clients in recent history. Using this data to support your company's CMO vetting process (or to understand your company's relative position to its CMO peers) will put you on the path toward a successful partnership.

A. SCHAFER

If you want to learn more about the report or how to participate, please contact Andrew Schafer, president, or Kate Hammeke, market research director, at Industry Standard Research by sending an email to andrews@isrreports.com or kateh@isrreports.com.

Survey Methodology: Industry Standard Research's Contract Manufacturing Quality Benchmarking research is conducted annually via an online survey. For the 2016 CMO Awards data, more than 80 contract manufacturers were evaluated on 26 different performance metrics. Research participants were recruited from biopharmaceutical companies of all sizes and are screened for decision-making influence and authority when it comes to working with contract manufacturing suppliers. **Respondents only evaluate companies with which they have worked on an outsourced project within the past 18 months.** This level of qualification ensures that quality ratings come from actual involvement with a business and that companies identified as leaders are backed by experiential data.

List Of Winners
Page 44-50

Company Profiles
Page 51-62

CMO LEADERSHIP AWARDS 2016

Life Science Leader's readership of pharmaceutical and biopharmaceutical executives have told us about their struggles in efficiently vetting potential CMO partners. In response to this input, *Life Science Leader* developed the CMO Leadership Awards.

Based on research from Industry Standard Research's Contract Manufacturing Quality Benchmarking annual online survey, more than 80 contract manufacturers were evaluated on 26 different performance metrics. Research participants were recruited from biopharmaceutical companies of all sizes and were screened for decision-making influence and authority when it comes to working with contract manufacturing suppliers. Respondents only evaluated companies with which they have worked on an outsourced project within the past 18 months. This level of qualification ensures that quality ratings come from actual involvement with a business and that companies identified as leaders are backed by experiential data. CMOs have an opportunity to win these awards in up to three groups of outsourcing respondents — Big Pharma, Small Pharma, and Overall (combined Big and Small Pharma).

WHAT ARE THE AWARDS?

ISR's survey participants were asked to provide an expectation rating for each CMO they have worked with in the past 18 months. Respondents answered over 45 questions per outsourcing category (small molecule, biologic, finished dose) and rated CMOs across 25 performance attributes. Points were then totaled for a combined score for each attribute, and a composite score for each core category was determined. Winning CMOs were determined when comparing their overall score vs. the competitive set.

To learn more about ISR's industry reports, customized research, or to be included in future CMO Leadership Awards annual surveys, visit isrreports.com or contact ISR at (919) 301-0106.

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CMO LEADERSHIP AWARDS 2016 CAPABILITIES

- All facilities fully owned
- Complementary core competencies to in-house or other manufacturing contractors
- Facility has most up-to-date manufacturing technologies
- Full range of manufacturing for the dosage forms we require
- Has capacity to meet our demands
- Offers innovative solutions
- Proven ability to manufacture API
- Provides regulatory support for filing
- Stability testing capabilities; storage capabilities

CAPABILITIES

TOP PERFORMERS

OVERALL

CMC Biologics
Flamma
Helsinn
AbbVie Contract Manufacturing
Pfizer CentreSource
PharmaCore
Dalton Pharma Services
Ash Stevens
Novasep
Kemwell

BIG PHARMA

Pfizer CentreSource
Novasep
GSK Contract Manufacturing

SMALL PHARMA

Pfizer CentreSource
Novasep
PharmaCore
Rentschler
Dalton Pharma Services

EXCEEDED CUSTOMER EXPECTATIONS

OVERALL

Paragon
Capsugel
Rentschler
Vetter
Cambrex
Samsung BioLogics
GSK Contract Manufacturing
AMPAC Fine Chemicals
Baxter BioPharma Solutions
Dr. Reddy's Custom Pharmaceutical Services

BIG PHARMA

Cambrex
CEPiA Sanofi
AAI Pharma Services Corp./ Cambridge Major Laboratories
Vetter
Dr. Reddy's Custom Pharmaceutical Services
Siegfried
AMPAC Fine Chemicals
Hetero

SMALL PHARMA

Paragon
AMRI
Cambrex
Patheon
GSK Contract Manufacturing

MET CUSTOMER EXPECTATIONS

OVERALL

Celltrion
SAI Life Sciences
AMRI
Boehringer Ingelheim
STA, A WuXi AppTec company
Corden Pharma
Patheon
Hetero
Xcelience
CEPiA Sanofi
Cook Pharmica
Fareva
Lonza
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PCI Synthesis

The terms "Small Pharma" and "Big Pharma" pertain to the outsourcing respondents, not the winners. "Overall" is a combination of Big and Small Pharma.

CMO LEADERSHIP AWARDS 2016
COMPATIBILITY

- Access to desired markets
- Accessible senior management
- Complementary core competencies to in-house or other manufacturing contractors
- Cultural fit
- Financial strength/stability
- Timely project communications
- Well-regarded within the industry

COMPATIBILITY

TOP PERFORMERS

OVERALL

CMC Biologics
Flamma
AbbVie Contract Manufacturing
PharmaCore
Helsinn
Pfizer CentreSource
Kemwell
Novasep
Ash Stevens

BIG PHARMA

Pfizer CentreSource
CEPiA Sanofi
Novasep

SMALL PHARMA

PharmaCore
Novasep
Pfizer CentreSource

EXCEEDED CUSTOMER EXPECTATIONS

OVERALL

Dalton Pharma Services
Paragon
Capsugel
Fareva
Samsung BioLogics
Cook Pharmica
Baxter BioPharma Solutions
Xcelience
Vetter
Cambrex
Celltrion
Boehringer Ingelheim
SAI Life Sciences

BIG PHARMA

Cambrex
Siegfried
Fareva
AAI Pharma Services Corp./
Cambridge Major Laboratories
Vetter
GSK Contract Manufacturing
Lonza
Samsung BioLogics

SMALL PHARMA

Dalton Pharma Services
Paragon
AMRI
PCI Synthesis
Patheon
Rentschler
Almac

MET CUSTOMER EXPECTATIONS

OVERALL

GSK Contract Manufacturing
AMRI
Rentschler
Corden Pharma
Halo Pharma
STA, A WuXi AppTec company
Lonza
Patheon
CEPiA Sanofi
Almac
Siegfried
AMPAC Fine Chemicals
PCI Synthesis
IDT Biologika
Hetero
Hospira One 2 One
Aptuit
AAI/Cambridge Major
Evonik
Sandoz
Catalent
Dr. Reddy's Custom
Pharmaceutical Services

BIG PHARMA

STA, A WuXi AppTec company
Dr. Reddy's Custom
Pharmaceutical Services
Baxter BioPharma Solutions
Boehringer Ingelheim
Hetero
Cook Pharmica
Corden Pharma
AMPAC Fine Chemicals
Evonik
Xcelience
Almac
Patheon
AMRI

SMALL PHARMA

Aptuit
Cambrex
GSK Contract Manufacturing
STA, A WuXi AppTec company
Lonza
SAI Life Sciences
Catalent
CEPiA Sanofi
AAI/Cambridge Major

CMO LEADERSHIP AWARDS 2016 EXPERTISE

- Ability to smoothly scale up manufacturing and transfer technology
- Experience level of staff
- Offers innovative solutions
- Provides regulatory support for filing
- Scientific knowledge
- Strong regulatory track record

EXPERTISE

TOP PERFORMERS

OVERALL

CMC Biologics
Flamma
AbbVie Contract Manufacturing
Helsinn
Pfizer CentreSource
Paragon
PharmaCore
Dalton Pharma Services
Ash Stevens
Novasep

BIG PHARMA

Pfizer CentreSource
Novasep
Vetter
CEPiA Sanofi

SMALL PHARMA

Dalton Pharma Services
PharmaCore
Novasep
Pfizer CentreSource

EXCEEDED CUSTOMER EXPECTATIONS

OVERALL

Vetter
Capsugel
Kemwell
Fareva
Cambrex
Baxter BioPharma Solutions
Rentschler
Boehringer Ingelheim
GSK Contract Manufacturing
AMRI
Xcelience

BIG PHARMA

Cambrex
AAI Pharma Services Corp./
Cambridge Major Laboratories
Hetero
Fareva
Siegfried
Lonza
Baxter BioPharma Solutions
GSK Contract Manufacturing
STA, A WuXi AppTec company
Dr. Reddy's Custom
Pharmaceutical Services
Boehringer Ingelheim

SMALL PHARMA

Paragon
Rentschler
AMRI
Cambrex
Patheon
Aptuit
GSK Contract Manufacturing

MET CUSTOMER EXPECTATIONS

OVERALL

Cook Pharmica
Lonza
Patheon
STA, A WuXi AppTec company
Hetero
Dr. Reddy's Custom
Pharmaceutical Services
CEPiA Sanofi
Celltrion
Siegfried
Aptuit
AMPAC Fine Chemicals
SAI Life Sciences
Almac
Corden Pharma
Hospira One 2 One
AAI/Cambridge Major
Catalent
Evonik
Sandoz
IDT Biologika
Samsung BioLogics
Piramal Pharma Solutions
Glatt Pharmaceutical Services
PCI Synthesis
NextPharma
Althea

BIG PHARMA

Evonik
Xcelience
AMRI
AMPAC Fine Chemicals
Patheon
Corden Pharma
Almac
Next Pharma

SMALL PHARMA

Almac
Dr. Reddy's Custom
Pharmaceutical Services
Catalent
PCI Synthesis
Lonza
CEPiA Sanofi
Piramal Pharma Solutions
STA, A WuXi AppTec company

The terms "Small Pharma" and "Big Pharma" pertain to the outsourcing respondents, not the winners. "Overall" is a combination of Big and Small Pharma.

CMO LEADERSHIP AWARDS 2016 QUALITY

- Right first-time measurements
- Strong regulatory track record
- Track record for meeting quality performance metrics
- Up-front contingency planning, risk management

QUALITY

TOP PERFORMERS

OVERALL

CMC Biologics
Helsinn
AbbVie Contract Manufacturing
PharmaCore
Paragon
Pfizer CentreSource
Dalton Pharma Services
Flamma
Ash Stevens

BIG PHARMA

Pfizer CentreSource
CEPiA Sanofi
Vetter

SMALL PHARMA

PharmaCore
Paragon
Pfizer CentreSource
Dalton Pharma Services
Novasep

EXCEEDED CUSTOMER EXPECTATIONS

OVERALL

Capsugel
Kemwell
Novasep
Baxter BioPharma Solutions
Vetter
Cambrex
Celltrion
Xcelience
Rentschler
CEPiA Sanofi
Boehringer Ingelheim
Patheon
STA, A WuXi AppTec company
Lonza
GSK Contract Manufacturing
Samsung BioLogics
Fareva
Dr. Reddy's Custom Pharmaceutical Services

BIG PHARMA

AAI Pharma Services Corp./ Cambridge Major Laboratories
Cambrex
Novasep
Dr. Reddy's Custom Pharmaceutical Services
Siegfried
Lonza
GSK Contract Manufacturing
STA, A WuXi AppTec company
Baxter BioPharma Solutions
Hetero

SMALL PHARMA

Cambrex
Rentschler
Patheon
CEPiA Sanofi
Almac

MET CUSTOMER EXPECTATIONS

OVERALL

Hospira One 2 One
Almac
Hetero
Siegfried
Cook Pharmica
SAI Life Sciences
Catalent
Aptuit
AMPAC Fine Chemicals
AAI/Cambridge Major
Halo Pharma
AMRI
PCI Synthesis
Sandoz
Piramal Pharma Solutions
Corden Pharma
NextPharma
IDT Biologika
Metrics
Evonik

BIG PHARMA

Fareva
Boehringer Ingelheim
Xcelience
Patheon
Evonik
Almac
Catalent
AMPAC Fine Chemicals
NextPharma
AMRI
Samsung BioLogics

SMALL PHARMA

GSK Contract Manufacturing
Aptuit
Catalent
Lonza
PCI Synthesis
STA, A WuXi AppTec company
Dr. Reddy's Custom Pharmaceutical Services
SAI Life Sciences
AMRI
Piramal Pharma Solutions

CMO LEADERSHIP AWARDS 2016 RELIABILITY

- All facilities fully owned
- Financial strength/stability
- Flexibility to adjust schedule for special requests
- Has capacity to meet our demands
- Reliable on-time delivery
- Timely project management
- Up-front contingency planning, risk management

RELIABILITY

TOP PERFORMERS

OVERALL

CMC Biologics
Flamma
AbbVie Contract Manufacturing
PharmaCore
Helsinn
Pfizer CentreSource
Dalton Pharma Services
Kemwell
Ash Stevens

BIG PHARMA

Pfizer CentreSource
Novasep

SMALL PHARMA

PharmaCore
Novasep
Dalton Pharma Services
Pfizer CentreSource

EXCEEDED CUSTOMER EXPECTATIONS

OVERALL

Paragon
Novasep
Samsung BioLogics
Cambrex
Capsugel
Cook Pharmica
Baxter BioPharma Solutions
SAI Life Sciences
Rentschler
AMPAC Fine Chemicals
Celltrion
Fareva

BIG PHARMA

CEPiA Sanofi
GSK Contract Manufacturing
Samsung BioLogics
Hetero
Siegfried
AAI Pharma Services Corp./
Cambridge Major Laboratories
Cambrex
Dr. Reddy's Custom
Pharmaceutical Services
STA, A WuXi AppTec company
Lonza

SMALL PHARMA

Paragon
Cambrex
Rentschler
PCI Synthesis
Almac
Patheon

MET CUSTOMER EXPECTATIONS

OVERALL

STA, A WuXi AppTec company
Boehringer Ingelheim
Xcelience
Vetter
Hetero
Hospira One 2 One
GSK Contract Manufacturing
Siegfried
Patheon
Corden Pharma
Lonza
Dr. Reddy's Custom
Pharmaceutical Services
Almac
AMRI
CEPiA Sanofi
AAI/Cambridge Major
PCI Synthesis
Catalent
Sandoz
Aptuit
Evonik
NextPharma
Halo Pharma
Pharmatek
IDT Biologika

BIG PHARMA

Vetter
Baxter BioPharma Solutions
Fareva
AMPAC Fine Chemicals
Evonik
Cook Pharmica
Boehringer Ingelheim
AMRI
NextPharma
Patheon

SMALL PHARMA

AMRI
SAI Life Sciences
Aptuit
CEPiA Sanofi
STA, A WuXi AppTec company
GSK Contract Manufacturing
Catalent
Lonza
AAI/Cambridge Major
Dr. Reddy's Custom
Pharmaceutical Services

The terms "Small Pharma" and "Big Pharma" pertain to the outsourcing respondents, not the winners. "Overall" is a combination of Big and Small Pharma.

CMO LEADERSHIP AWARDS

INDIVIDUAL ATTRIBUTE AWARDS

The Individual Attribute Awards were developed as a result of many conversations we have had with the readers of *Life Science Leader* and the attendees at our Outsourced Pharma Events. These conversations uncovered common attributes that sponsor companies identified as being imperative when choosing a supplier and deciding to continue doing business with a supplier.

They were often referred to as the ever-important "intangibles" a supplier brings to the table. Outside of the core metrics of quality, reliability, compatibility, capabilities, and expertise, these attributes were what our readers identified as being most important, and as such, we felt it was important to share the data with other sponsor companies.

ACCESSIBLE SENIOR MANAGEMENT

TOP PERFORMERS

Flamma
CMC Biologics
PharmaCore
Fareva
Ash Stevens
AbbVie Contract Manufacturing
Helsinn
Paragon
PCI Synthesis
Samsung BioLogics

EXCEEDED CUSTOMER EXPECTATIONS

Pfizer CentreSource
Kemwell
Novasep
Dalton Pharma Services
Xcelience
Corden Pharma
Halo Pharma
Recipharm
Cook Pharmica
Vetter
Siegfried
STA, A WuXi AppTec company
Celltrion
CEPiA Sanofi
Aptuit
Baxter BioPharma Solutions

CULTURAL FIT

TOP PERFORMERS

CMC Biologics
Flamma
AbbVie Contract Manufacturing
PharmaCore
Pfizer CentreSource
Ash Stevens
Paragon
Kemwell
Novasep

EXCEEDED CUSTOMER EXPECTATIONS

Helsinn
Xcelience
Fareva
Dalton Pharma Services
Capsugel
CEPiA Sanofi
AMPAC Fine Chemicals
Boehringer Ingelheim
SAI Life Sciences
Rentschler
Cambrex

STATE-OF-THE-ART

Sponsored by ThermoFisher SCIENTIFIC

TOP PERFORMERS

CMC Biologics
AbbVie Contract Manufacturing
Flamma
Pfizer CentreSource
Helsinn
Ash Stevens
Samsung BioLogics
Novasep

EXCEEDED CUSTOMER EXPECTATIONS

Kemwell
Vetter
Capsugel
Paragon
Cambrex
Cook Pharmica
Rentschler
PharmaCore
Boehringer Ingelheim
Baxter BioPharma Solutions
Celltrion
Glatt Pharmaceutical Services
STA, A WuXi AppTec company
AMPAC Fine Chemicals
Evonik
Dalton Pharma Services
Dr. Reddy's Custom Pharmaceutical Services
GSK Contract Manufacturing
SAI Life Sciences
Sandoz

INNOVATION

Sponsored by ThermoFisher SCIENTIFIC

TOP PERFORMERS

Flamma
CMC Biologics
Paragon
Pfizer CentreSource
AbbVie Contract Manufacturing
Helsinn
Vetter
Novasep
Ash Stevens
Dalton Pharma Services
PharmaCore

EXCEEDED CUSTOMER EXPECTATIONS

Capsugel
AMRI
Cambrex
Kemwell
Baxter BioPharma Solutions
Cook Pharmica
CEPiA Sanofi
Fareva
STA, A WuXi AppTec company

CMO LEADERSHIP AWARDS

INDIVIDUAL ATTRIBUTE AWARDS

ON-TIME DELIVERY

TOP PERFORMERS

CMC Biologics
AbbVie Contract Manufacturing
Flamma
Dalton Pharma Services
Paragon
Pfizer CentreSource
Ash Stevens
Kemwell
PharmaCore
Helsinn

EXCEEDED CUSTOMER EXPECTATIONS

Baxter BioPharma Solutions
Hetero
Samsung BioLogics
Cambrex
Rentschler
Capsugel
NextPharma
PCI Synthesis
Novasep
Dr. Reddy's Custom Pharmaceutical Services
AMPAC Fine Chemicals

RIGHT FIRST TIME

TOP PERFORMERS

CMC Biologics
AbbVie Contract Manufacturing
Helsinn
Paragon
Dalton Pharma Services
PharmaCore
Pfizer CentreSource
Flamma

EXCEEDED CUSTOMER EXPECTATIONS

Kemwell
Baxter BioPharma Solutions
Capsugel
Ash Stevens
Novasep
Hospira One 2 One
Boehringer Ingelheim
Dr. Reddy's Custom Pharmaceutical Services
Celltrion
Siegfried
Rentschler
Patheon
Cambrex
STA, A WuXi AppTec company
Hetero
Xcelience
AMPAC Fine Chemicals
Samsung BioLogics
Cook Pharmica
Vetter
CEPiA Sanofi

STRENGTH OF SCIENCE

TOP PERFORMERS

CMC Biologics
Flamma
AbbVie Contract Manufacturing
Pfizer CentreSource
PharmaCore
Fareva
Novasep

EXCEEDED CUSTOMER EXPECTATIONS

Helsinn
Vetter
Dalton Pharma Services
Paragon
Capsugel
Ash Stevens
Cook Pharmica
Cambrex
Kemwell
Lonza
Baxter BioPharma Solutions
CEPiA Sanofi
Hetero
Boehringer Ingelheim
Siegfried
Dr. Reddy's Custom Pharmaceutical Services
AMRI

REPUTATION

TOP PERFORMERS

CMC Biologics
PharmaCore
Helsinn
Vetter
AbbVie Contract Manufacturing
Pfizer CentreSource
Flamma
Paragon

EXCEEDED CUSTOMER EXPECTATIONS

Novasep
Dalton Pharma Services
Capsugel
Ash Stevens
Cambrex
GSK Contract Manufacturing
Baxter BioPharma Solutions
Lonza
Boehringer Ingelheim
Cook Pharmica
Kemwell
Xcelience
SAI Life Sciences
Patheon

AAIPHARMA
CAMBRIDGE MAJOR LABORATORIES

CATEGORIES WON

AAIPharma Services Corp./ Cambridge Major Laboratories, Inc.

Wilmington, NC
www.aaipharma.com and www.c-mlabs.com

+1 910 254 7000
Catherine Hanley
Catherine.Hanley@aaipharma.com
Key locations: Charleston, SC; Germantown, WI; Wilmington, NC

DRUG TYPE:
Pharmaceuticals, Biopharmaceuticals

DRUG LIFE CYCLE STAGES:
Research & Development: Discovery, Preclinical, Clinical (Phase 1, Phase 2, Phase 3)
Drug Substance Production: Primary Process Development, Drug Substance Production
Formulated Drug Production: Dosage Form Development, Dosage Form Production, Packaging

SERVICES & CAPABILITIES: aseptic fill/finish, capsules, controlled substances, creams & ointments, cytotoxic & high potency compounds, generics, injectables, liquids, lyophilized products, non-sterile, ophthalmics, OTC, parenterals (large volume), parenterals (small volume), peptides, powders (non-sterile), powders (sterile), proteins, soft gels, solid dose, solutions & suspensions, sterile, sustained release, syringes (prefilled), topicals

STEPHAN KUTZER
CEO

"We are extremely excited and honored to be nominated for these prestigious awards. Our company has put forth significant effort and investment to continuously improve our performance across these critical areas – quality, reliability, capabilities, expertise, and compatibility. AAI/CML has also been focusing on our clients' individual unique objectives and on connecting with our clients at every organizational level. With all these significant improvements, AAI/CML has increased its compatibility with our clients' needs to provide innovative solutions for their drug development and manufacturing success toward the commercialization of their drugs."

abbvie

CATEGORIES WON

AbbVie

North Chicago, IL
www.abbviecontractmfg.com

+1 847 938 8524
Michelle Calhoun
michelle.calhoun@abbvie.com
Key locations: Ludwigshafen, Germany; Sligo & Cork, Ireland; Campoverde, Italy; Barceloneta, Puerto Rico; Worcester, MA and Lake County, IL, U.S.A.

DRUG TYPE:
Pharmaceuticals, Biopharmaceuticals

DRUG LIFE CYCLE STAGES:
Research & Development: Clinical (Phase 1, Phase 2, Phase 3)
Drug Substance Production: Primary Process Development, Drug Substance Production
Formulated Drug Production: Dosage Form Development, Dosage Form Production, Packaging

SERVICES & CAPABILITIES: aseptic fill/finish, capsules, controlled substances, creams & ointments, cytotoxic & high potency compounds, hot melt extrusion, injectables, liquids, non-sterile, OTC, parenterals (large volume), parenterals (small volume), proteins, semisolids, solid dose, sustained release, syringes (prefilled), vaccines

INDIVIDUAL ATTRIBUTE AWARDS: accessible senior managment, cultural fit, innovation, on-time, reputation, right first time, state-of-the-art, strength of science

AZITA SALEKI-GERHARDT, PH.D.
SVP & President, Operations

"AbbVie is honored to be recognized as a top contract manufacturer by *Life Science Leader*. It is a privilege to achieve the top ranking in all five award criteria: quality, expertise, capabilities, compatibility, reliability. We are extremely proud of this achievement and what it represents about our commitment to our CMO clients. We provide the highest quality support and services to our partners and their patients."

AMRI®
Albany Molecular Research Inc.

CATEGORIES WON

Albany Molecular Research Inc.

Albany, NY
www.amriglobal.com

+1 518 512 2020
Dean Bornilla
dean.bornilla@amriglobal.com
Key locations: Albany, NY, Rensselaer, NY, Burlington, MA, Grafton, WI, Albuquerque, NM, U.S.A; Glasgow Lanarkshire, Scotland

DRUG TYPE:
Pharmaceuticals, Biopharmaceuticals

DRUG LIFE CYCLE STAGES:
Research & Development: Discovery, Preclinical, Clinical (Phase 1, Phase 2, Phase 3)
Drug Substance Production: Primary Process Development, Drug Substance Production
Formulated Drug Production: Dosage Form Development, Dosage Form Production

SERVICES & CAPABILITIES: aseptic fill/finish, controlled substances, cytotoxic & high potency compounds, generics, injectables, lyophilized products, ophthalmics, parenterals (large volume), parenterals (small volume), solutions & suspensions, sterile, syringes (prefilled)

INDIVIDUAL ATTRIBUTE AWARDS: innovation, strength of science

WILLIAM S. MARTH
President & CEO

"We are honored to have been recognized once again as a CMO Leadership Award winner, this year in the categories of expertise, capabilities, and compatibility. These awards are a testament to the hard work of all of our employees at AMRI and their loyalty and dedication to our customers and their projects."

ALMAC
Partnering to Advance Human Health

CATEGORIES WON

Almac Group

Craigavon, Co. Armagh, UK
www.almacgroup.com

+02838332200
Jennifer Forsythe
jennifer.forsythe@almacgroup.com
Key locations: Craigavon, UK; Singapore; Edinburgh; North Carolina, Pennsylvania, San Francisco, U.S.A.

DRUG TYPE:
Pharmaceuticals, Biopharmaceuticals

DRUG LIFE CYCLE STAGES:
Research & Development: Discovery, Preclinical, Clinical (Phase 1, Phase 2, Phase 3)
Drug Substance Production: Primary Process Development, Drug Substance Production
Formulated Drug Production: Dosage Form Development, Dosage Form Production, Packaging, Logistics

SERVICES & CAPABILITIES: aseptic fill/finish, capsules, controlled substances, creams & ointments, cytotoxic & high potency compounds, generics, liquids, lyophilized products, nonsterile, OTC, parenterals (large volume), parenterals (small volume), peptides, powders (nonsterile), powders (sterile), proteins, semisolids, soft gels, solid dose, solutions & suspensions, sustained release, topicals

ALAN ARMSTRONG
CEO

"We are delighted to have received yet another CMO Leadership Award for these three key categories. We pride ourselves on our ability to not only meet but exceed expectations to our global clients by ensuring that we provide exceptional and reliable quality in all aspects of our work. These awards recognize that quality determines the extent of our commitment and success."

AMPAC™ FINE CHEMICALS

CATEGORIES WON

AMPAC Fine Chemicals

Rancho Cordova, CA
www.ampacfinechemicals.com

+1 916 357 6880
Patrick Park
afcbusdev@apfc.com
Key locations: Rancho Cordova, CA; La Porte, TX

DRUG TYPE:
Pharmaceuticals

DRUG LIFE CYCLE STAGES:
Research & Development: Clinical (Phase 1, Phase 2, Phase 3)
Drug Substance Production: Primary Process Development, Drug Substance Production

SERVICES & CAPABILITIES: APIs and HPAPIs, controlled substances, cytotoxic & high potency compounds, fine chemicals, generics, peptides, registered intermediates

INDIVIDUAL ATTRIBUTE AWARDS: cultural fit, on-time, right first time, state-of-the-art

ASLAM MALIK
President & CEO

"AMPAC Fine Chemicals (AFC) has established a heritage of successful transition from clinical to commercial production, demanding production quantity and highly energetic APIs.

AFC is a recognized partner supporting FDA Pre-Approval Inspections for complex drug formulations, commercial drug products, controlled substances, high potency, and energetic compounds.

AFC has an aggressive growth program focused on medium scale production quickly configured for specific programs as well as large-scale capacity for major batch and continuous operations."

aptuit

CATEGORIES WON

Aptuit

Greenwich, CT
www.aptuit.com

+1 855 4 APTUIT [427 8848]
Dan Conlon
dan.conlon@aptuit.com
Key locations: Veroa, Italy; Oxford, UK

DRUG TYPE:
Pharmaceuticals

DRUG LIFE CYCLE STAGES:
Research & Development: Discovery, Preclinical
Drug Substance Production: Primary Process Development
Formulated Drug Production: Dosage Form Development

SERVICES & CAPABILITIES: API development & manufacture, physical & analytical chemistry

INDIVIDUAL ATTRIBUTE AWARDS: accessible senior management

JONATHAN GOLDMAN
CEO

"Customers have noted our unique capabilities in integrated discovery, integrated CMC, and integrated development. Our growth program led to a significant increase in capacity allowing us to deliver more high-quality integrated CMC and help our customers increase their chances of successful IND filing. We are focused on helping our customers discover, develop, and produce drugs with very high quality, whilst minimizing operational risks. We remain best in class for scientific quality, speed, and cost."

Ash Stevens

CATEGORIES WON

Ash Stevens

Riverview, MI
www.ashstevens.com

+1 734 282 3370
James Hamby
jhamby@ashstevens.com
Key locations: Detroit and Riverview, MI

DRUG TYPE:
Pharmaceuticals, Biopharmaceuticals

DRUG LIFE CYCLE STAGES:
Research & Development: Discovery, Preclinical, Clinical (Phase 1, Phase 2, Phase 3)
Drug Substance Production: Primary Process Development, Drug Substance Development & Manufacturing

SERVICES & CAPABILITIES: API for toxicology studies, clinical trials, post-approval manufacturing, cGMP manufacture of Highly Potent Active Pharmaceutical Ingredients (HPAPIs), comprehensive analytical support including methods development & methods validation, process development & scale-up, stability testing, global regulatory support including document support for all regulatory filings (INDs, NDAs, DMFs, CTD)

INDIVIDUAL ATTRIBUTE AWARDS: accessible senior managment, cultural fit, innovation, on-time, reputation, right first time, state-of-the-art, strength of science

STEPHEN MUNK
CEO

"Recognition in all five categories by *Life Science Leader* is a testament to the Ash Stevens team. It is the steadfast commitment to our customers' unique drug programs that makes being ranked as a top CMO an absolute honor for us all. This acknowledgement is affirmation of our level of engagement with our customers and our top quality service."

Baxter

CATEGORIES WON

Baxter BioPharma Solutions

Deerfield, IL
www.baxterbiopharmasolutions.com

+1 800 4-BAXTER [422 9837]
Laura Salo
laura_salo@baxter.com
Key locations: Bloomington, IN, Round Lake, IL, U.S.A.; Halle (Westfalen), Germany

DRUG TYPE:
Pharmaceuticals

DRUG LIFE CYCLE STAGES:
Research & Development: Clinical (Phase 1, Phase 2, Phase 3)
Formulated Drug Production: Dosage Form Development, Dosage Form Production, Packaging

SERVICES & CAPABILITIES: aseptic fill/finish, cartridges, cytotoxic & high potency compounds, generics, injectables, liquids, lyophilized products, parenterals (large volume), parenterals (small volume), powders (sterile), sterile, syringes (prefilled), vaccines

INDIVIDUAL ATTRIBUTE AWARDS: accessible senior managment, innovation, on-time, reputation, right first time, state-of-the-art, strength of science

BUKHARD WICHERT
Vice President, Maufacturing

"Baxter's heritage is built on 80+ years of parenteral expertise, including over 30 years of CMO experience. Combining scientific expertise, innovative products, global quality and regulatory systems, and an international manufacturing network, Baxter provides a firm foundation for the BioPharma Solutions (BPS) contract manufacturing business. By leveraging this deep expertise in every functional area, BPS can serve customers globally and provide vital products to patients who benefit from our therapies."

Boehringer Ingelheim

CATEGORIES WON

Boehringer Ingelheim Biopharmaceuticals GmbH

Ingelheim am Rhein, Germany
www.bioxcellence.com

+49 6132 77 0
Pauline Bronzel
bioxcellence@boehringer-ingelheim.com
Key locations: Biberach, Germany; Vienna, Austria; Fremont, U.S.A.; Shanghai, China

DRUG TYPE:
Biopharmaceuticals

DRUG LIFE CYCLE STAGES:
Research & Development: Preclinical, Clinical (Phase 1, Phase 2, Phase 3)
Drug Substance Production: Primary Process Development, Drug Substance Production
Formulated Drug Production: Dosage Form Development, Dosage Form Production

SERVICES & CAPABILITIES: aseptic fill/finish, cartridges, liquids, lyophilized products, peptides, proteins, syringes (prefilled)

INDIVIDUAL ATTRIBUTE AWARDS: cultural fit, reputation, right first time, state-of-the-art, strength of science

Cambrex

CATEGORIES WON

East Rutherford, NJ
www.cambrex.com

+1 201 804 3000
Alex Maw
alex.maw@cambrex.com
Key locations: Charles City, IA, U.S.A.; Karlskoga, Sweden; Paullo (Milan) Italy; Wiesbaden, Germany; Tallinn, Estonia

DRUG TYPE:
Pharmaceuticals

DRUG LIFE CYCLE STAGES:
Research & Development: Clinical (Phase 2, Phase 3)
Drug Substance Production: Primary Process Development, Drug Substance Production

SERVICES & CAPABILITIES: biocatalysis, controlled substances, cytotoxic & high potency compounds, generics, Innovator APIs (custom development/contract manufacturing), intermediates

INDIVIDUAL ATTRIBUTE AWARDS: cultural fit, innovation, on-time, reputation, right first time, state-of-the art, strength of science

STEVEN M. KLOSK
President & CEO

"I am extremely proud that Cambrex has for the second consecutive year been selected as a winner of the CMO Leadership Awards. Cambrex has a strong customer focus and a commitment to world-class quality. Receiving the awards in the five critical categories demonstrates our continued commitment to our customers and recognition by the pharmaceutical industry."

Capsugel Dosage Form Solutions

CATEGORIES WON

Morristown, NJ
www.capsugel.com

+1 862 242 1700
Ajay Damani
ajay.damani@capsugel.com
Key locations: Bend, OR, Greenwood, SC, U.S.A.; Bornem, Belgium; Colmar, France; Delhi, India; Sagamihara, Japan

DRUG TYPE:
Pharmaceuticals

DRUG LIFE CYCLE STAGES:
Research & Development: Discovery; Preclinical, Clinical (Phase 1, Phase 2, Phase 3)
Drug Substance Production: Primary Process Development, Drug Substance Production
Formulated Drug Production: Dosage Form Development, Dosage Form Production, Packaging, Logistics

SERVICES & CAPABILITIES: bioavailability enhancement technologies, spray-dried dispersions, api micronization, modified & targeted release, functional capsule technologies, fixed dose combinations, bi/tri layered tablets, multiparticulate technologies, liquid-fill hard capsule technologies, soft gels, cytotoxic & high potency compounds, controlled substances, proteins, inhalation formulations, encapsulation, CTM manufacture & packaging

INDIVIDUAL ATTRIBUTE AWARDS: cultural fit, innovation, on-time, reputation, right first time, state-of-the-art, strength of science

AMIT PATEL
President

"Each of us at Capsugel Dosage Form Solutions strives to create exceptional value for – and earn the trust of – our customers every day. Based on world-class science and engineering, our technology breadth, and formulation expertise, enables Capsugel product development teams to identify and employ the optimal technology for any problem statement. Our integrated business model allows us to design, develop, scale up, and commercially manufacture innovative dosage forms in any market presentation."

CEPiA Sanofi

CATEGORIES WON

Bridgewater, NJ
www.cepia-sanofi.com

+ 1 908 981 8346
Melanie Durand
melanie.durand@sanofi.com
Key locations: Vertolaye, France; Aramon, France; Sisteron, France; Elbeuf, France; Ujpest, Hungary; Frankfurt, Germany

DRUG TYPE:
Pharmaceuticals, Biopharmaceuticals

DRUG LIFE CYCLE STAGES:
Research & Development: Clinical (Phase 3)
Drug Substance Production: Drug Substance Production
Formulated Drug Production: Dosage Form Production, Packaging

SERVICES & CAPABILITIES: aseptic fill/finish, capsules, cartridges, creams & ointments, cytotoxic & high potency compounds, gels, generics, injectables, lyophilized products, non-sterile, ophthalmics, OTC, parenterals (large volume), parenterals (small volume), peptides, powders (non-sterile), proteins, semisolids, solid dose, sterile, sustained release, syringes (prefilled), topicals, vaccines

INDIVIDUAL ATTRIBUTE AWARDS: accessible senior management, cultural fit, innovation, right first time, strength of science

JACQUES TAVERNIER
Vice President

"I am very honored that CEPiA is recognized for the second year in a row and I strongly believe this is the result of the focus of our network on delivering high quality standards to its customers i.e., 'CEPiA's trademark'."

CATEGORIES WON

CMC Biologics

Bothell, WA
www.cmcbiologics.com

+1 425 485 1900
Robert Broeze
bbroeze@cmcbio.com
Key locations: Bothell, WA, Berkeley, CA, U.S.A.; Soeborg, Copenhagen, Denmark

DRUG TYPE:
Biopharmaceuticals

DRUG LIFE CYCLE STAGES:
Research & Development: Preclinical, Clinical (Phase 1, Phase 2, Phase 3)
Drug Substance Production: Primary Process Development, Drug Substance Production

SERVICES & CAPABILITIES: lyophilized products, proteins, vaccines

INDIVIDUAL ATTRIBUTE AWARDS: accessible senior managment, cultural fit, innovation, on-time, reputation, right first time, state-of-the-art, strength of science

GUSTAVO MAHLER
President & CEO

"The CMC Biologics' team is honored to receive this prestigious award in all five categories as recognized by our customers and the industry as a whole. Our customers rely on us to consistently provide the highest quality standards and forward-thinking facility designs to bring them clinical and commercial success. We are dedicated to ensuring our customers have access to senior management – throughout the project – and any challenges are met with sound solutions. Right. On Time."

CATEGORIES WON

Cook Pharmica LLC

Bloomington, IN
www.cookpharmica.com

+1 877 312 COOK [2665]
Cory Lewis
busdev@cookpharmica.com
Key locations: Bloomington, IN

DRUG TYPE:
Pharmaceuticals, Biopharmaceuticals

DRUG LIFE CYCLE STAGES:
Drug Substance Production: Primary Process Development, Drug Substance Production
Formulated Drug Production: Dosage Form Development, Dosage Form Production, Packaging

SERVICES & CAPABILITIES: aseptic fill/finish, biologics, cartridges, mammalian cell culture, generics, injectables, liquids, lyophilized products, parenterals (large volume), parenterals (small volume), proteins, sterile, syringes (prefilled), vaccines

INDIVIDUAL ATTRIBUTE AWARDS: accessible senior management, innovation, reputation, right first time, state-of-the-art, strength of science

TEDD GREEN
President

"At Cook Pharmica, our commitment to our clients and their patients remains at the forefront of our business. Through our continued focus on quality, flexibility, and reliability, we are able to become a strategic partner of choice for our clients. To ensure exceptional service, we remain heavily invested in our people, processes, and facility. Once again, we are honored to be recognized through the CMO Leadership Awards."

CATEGORIES WON

Dalton Pharma Services

Toronto, ON, Canada
www.dalton.com

+1 416 661 2102
Kavvita Santilli
KSantilli@dalton.com
Key locations: Toronto, ON

DRUG TYPE:
Pharmaceuticals

DRUG LIFE CYCLE STAGES:
Research & Development: Discovery, Preclinical, Clinical (Phase 1, Phase 2, Phase 3)
Drug Substance Production: Primary Process Development, Drug Substance Production
Formulated Drug Production: Dosage Form Development, Dosage Form Production

SERVICES & CAPABILITIES: aseptic fill/finish, capsules, controlled substances, creams & ointments, gels, generics, injectables, liquids, lyophilized products, non-sterile, ophthalmics, parenterals (small volume), peptides, powders (non-sterile), powders (sterile), semisolids, soft gels, solid dose, solutions & suspensions, sterile, sustained release, syringes (prefilled), topicals, vaccines

INDIVIDUAL ATTRIBUTE AWARDS: accessible senior management, cultural fit, innovation, on-time, reputation, right first time, state-of-the-art, strength of science

PETER PEKOS
President & CEO

"This award is especially satisfying after 30 years supporting our clients with comprehensive drug discovery, development, and manufacturing services. Dalton's employees support our clients' programs in some of the most technically challenging areas of science. This award recognizes Dalton's management team's success in building a culture of excellence by bringing innovation to our clients' drug development programs."

FAREVA®
Passion for action

CATEGORIES WON

Fareva

Tournon sur Rhône, France
www.fareva.com

+1 919 768 6858
George Hlass
ghlass.usa@fareva.com
Key locations: France, Germany, Italy, United States

DRUG TYPE:
Pharmaceuticals

DRUG LIFE CYCLE STAGES:
Research & Development: Clinical (Phase 2, Phase 3)
Drug Substance Production: Primary Process Development, Drug Substance Production
Formulated Drug Production: Dosage Form Development, Dosage Form Production, Packaging

SERVICES & CAPABILITIES: aseptic fill/finish, capsules, controlled substances, creams & ointments, cytotoxic & high potency compounds, gels, generics, injectables, liquids, lyophilized products, non-sterile, ophthalmics, OTC, parenterals (large volume), parenterals (small volume), powders (non-sterile), powders (sterile), semisolids, solid dose, solutions & suspensions, sterile, sustained release, syringes (prefilled), topicals

INDIVIDUAL ATTRIBUTE AWARDS: accessible senior management, cultural fit, innovation, strength of science

BERNARD FRAISSE
President & CEO

"Fareva's success in contract manufacturing for our API and Pharma customers is based on the experience and the creativity of our teams in development, manufacturing, and regulatory affairs and they allow us to consistently provide innovative solutions.

Besides flawless and reliable supply, Fareva has established a position as a long-term preferred supplier by building relationships based on clear and open communications, vital to continuously meeting the wide-ranging needs of our customers."

Flamma

CATEGORIES WON

FLAMMA

Chignolo d'Isola, Bergamo, Italy
www.flammagroup.com

+011-39 035 4991811
Kenneth Drew
ken.drew@flammagroup.com
Key locations: Chignolo di'Isola, Bergamo, Italy (cGMP), Isso, Bergamo, Italy (cGMP), Dalian, China (non-cGMP)

DRUG TYPE:
Pharmaceuticals

DRUG LIFE CYCLE STAGES:
Research & Development: Preclinical, Clinical (Phase 1, Phase 2, Phase 3)
Drug Substance Production: Primary Process Development, Drug Substance Production

SERVICES & CAPABILITIES: cGMP manufacturer of APIs, NCEs, RSMs, key intermediates, building blocks, starting materials, generics, peptides, powders (sterile)

INDIVIDUAL ATTRIBUTE AWARDS: accessible senior management, cultural fit, innovation, on-time, reputation, right first time, state-of-the-art, strength of science

GIAN PAOLO NEGRISOLI
President & CEO

"Flamma is thankful to be recognized by those in the industry to receive five 2016 CMO Leadership Awards. The recognition is evidence that Flamma consistently works with our customers by treating them as if they are family. Flamma relies on its expertise in high value chiral materials (specifically, amino acid related materials) to be a difference maker and problem solver for those difficult projects. When it matters most, pharma and biotech companies turn to Flamma!"

gsk GlaxoSmithKline

CATEGORIES WON

GlaxoSmithKline
Contract Manufacturing

Brentford, Middlesex, UK
www.gsk.com

Russell Harris
russell.b.harris@gsk.com
Key locations: Australia, China, Europe, Japan, Middle East, North America, South America

DRUG TYPE:
Pharmaceuticals, Biopharmaceuticals

DRUG LIFE CYCLE STAGES:
Research & Development: Clinical (Phase 2, Phase 3)
Drug Substance Production: Primary Process Development, Drug Substance Production
Formulated Drug Product: Dosage Form Development, Dosage Form Production, Packaging, Logistics

SERVICES & CAPABILITIES: aseptic fill/finish, capsules, controlled substances, creams & ointments, cytotoxic & high potency compounds, foams, gels, generics, injectables, liquids, lyophilized products, non-sterile, ophthalmics, OTC, parenterals (large volume), parenterals (small volume), peptides, powders (sterile), proteins, semisolids, solid dose, solutions & suspensions, sterile, sustained release, syringes (prefilled), topicals

INDIVIDUAL ATTRIBUTE AWARDS: reputation, state-of-the-art

RUSSELL HARRIS
Director, Business Development & Third Party Sales

"Once again, we are thrilled to be recognized as a company that offers a sustainable, robust value proposition in the field of contract manufacturing. But more importantly, we are delighted to be offering patients access to our best-in-class integrated supply chains and development capabilities. We look forward to another successful year."

CATEGORIES WON

Helsinn Advanced Synthesis SA

Biasca, Switzerland
www.helsinn.com

+011 41 91 873 94 00
Sandra Moro
Sandra.Moro@helsinn.com
Key locations: Biasca, Switzerland

DRUG TYPE:
Pharmaceuticals

DRUG LIFE CYCLE STAGES:
Research & Development: Clinical (Phase 1, Phase 2, Phase 3)
Drug Substance Production: Primary Process Development, Drug Substance Production

SERVICES & CAPABILITIES: controlled substances, cytotoxic & high potency compounds, generics, ophthalmics, peptides, powders (non-sterile)

INDIVIDUAL ATTRIBUTE AWARDS: accessible senior management, cultural fit, innovation, on-time, reputation, right first time, state-of-the-art, strength of science

WALDO MOSSI
General Manager

"The Helsinn Group is celebrating its 40th anniversary in 2016 and believes its core values of respect, integrity, and quality have been the backbone of four decades of success in helping patients enjoy a better quality of life. These core values are echoed in the CMO Leadership categories and Helsinn is honored to be the recipient of awards in the following categories: quality, reliability, capabilities, expertise, and compatibility."

CATEGORIES WON

Hetero Labs Limited

Hyderabad, Telangana, India
www.heteroworld.com

+91 40 23704923/24/25
Dr Vasudev Jadhav
vasudev.j@heterodrugs.com
Key locations: Hyderabad, Vishakapatnam, Baddi, Pune

DRUG TYPE:
Pharmaceuticals, Biopharmaceuticals

DRUG LIFE CYCLE STAGES:
Research & Development: Discovery, Preclinical, Clinical (Phase 1, Phase 2, Phase 3)
Drug Substance Production: Primary Process Development, Drug Substance Production
Formulated Drug Production: Dosage Form Development, Dosage Form Production, Packaging, Logistics

SERVICES & CAPABILITIES: capsules, generics, injectables, liquids, soft gels, solid dose

INDIVIDUAL ATTRIBUTE AWARDS: on-time, right first time, strength of science

B PARADHASARADHI REDDY
Chairman & Managing Director

"In a span of over two decades, we have successfully emerged as one of India's leading generic pharmaceutical companies and one of the world's largest producers of anti-retroviral drugs for the treatment of HIV/AIDS. Started as an API manufacturer at the nascent stage, we evolved our businesses and are now focusing on generics, biosimilars and CPS. Our company is recognized for its strengths in research and development, manufacturing, and commercialization for various products."

CATEGORIES WON

Kemwell Biopharma

Morrisville, NC
www.kemwellbiopharma.com

+1 919 884 2064
Gregory Downs
gregory.downs@cirruspharm.com
Key locations: Bangalore, India; Uppsula, Sweden; Research Triangle Park, North Carolina, U.S.A.

DRUG TYPE:
Pharmaceuticals, Biopharmaceuticals

DRUG LIFE CYCLE STAGES:
Research & Development: Discovery, Preclinical, Clinical (Phase 1, Phase 2, Phase 3)
Formulated Drug Production: Dosage Form Development, Dosage Form Production, Packaging

SERVICES & CAPABILITIES: aseptic fill/finish, capsules, creams & ointments, gels, generics, inhaled dosage forms, injectables, liquids, lyophilized products, nonsterile, OTC, parenterals (large volume), parenterals (small volume), peptides, powders (non-sterile), proteins, semisolids, solid dose, solutions & suspensions, sterile, sustained release, topicals

INDIVIDUAL ATTRIBUTE AWARDS: accessible senior management, cultural fit, innovation, on-time, reputation, right first time, state-of-the-art, strength of science

ANURAG BAGARIA
Chariman & Managing Director

"We would like to thank our customers and the *Life Science Leader* for recognizing Kemwell as a winner in all five categories. We look forward to serving our current and new customers with increased depth of services in 2016 and support them to bring their high quality products to the patients. We are launching GMP manufacturing for clinical batches from our North Carolina site especially for non-sterile inhaled products (MDI, DPI, Nasal), oral liquids, topicals, and oral solids."

Lonza

CATEGORIES WON

Lonza

Basel, Switzerland
www.lonza.com

+41 61 316 81 11
Sean Diver
sean.diver@lonza.com
Key locations: Houston, TX, Portsmouth, NH, Walkersville, MD, U.S.A.; Porriño, Spain; Slough, UK

DRUG TYPE:
Biopharmaceuticals

DRUG LIFE CYCLE STAGES:
Research & Development: Discovery, Preclinical, Clinical (Phase 1, Phase 2, Phase 3)
Drug Substance Production: Primary Process Development, Drug Substance Production

SERVICES & CAPABILITIES: cytotoxic & high potency compounds, peptides, proteins

INDIVIDUAL ATTRIBUTE AWARDS: reputation, strength of science

RICHARD RIDINGER
CEO

"With these awards, Lonza is being recognized for our quality initiatives, reliability, expertise, and compatibility. In 2015 our efforts resulted in successful regulatory inspections and customer audits at our cGMP sites, supporting our rank as a reliable partner. We strive continuously to reach the next level of excellence in commercial and innovation activities to help our customers' value chains. We are a more customer-focused and market-driven organization and believe our high rankings reflect this change."

novasep

passion & smart processes

CATEGORIES WON

NOVASEP

Lyon, France
www.novasep.com

+33 437 282 030
Andrew Brennan
andrew.brennan@novasep.com
Key locations: Le Mans, France; Mourenx, France; Pompey, France; Leverkusen, Germany; Seneffe, Belgium; Boothwyn, PA, U.S.A.

DRUG TYPE:
Pharmaceuticals, Biopharmaceuticals

DRUG LIFE CYCLE STAGES:
Research & Development: Clinical (Phase 1, Phase 2, Phase 3)
Drug Substance Production: Primary Process Development, Drug Substance Production

SERVICES & CAPABILITIES: ADC payloads, chromatography, CMO services, cytotoxic & high potency compounds, generics, hazardous chemistry, mAbs, peptides, proteins, purification, vaccines, viral vectors

INDIVIDUAL ATTRIBUTE AWARDS: accessible senior management, cultural fit, innovation, on-time, reputation, right first time, state-of-the-art, strength of science

THIERRY VAN NIEUWENHOVE
President, Synthesis Business Unit

"Sincere thanks to all the customers and partners who voted for us in these 15 categories. Our commitment and efforts in delivering first-class service to our customers have been recognized. For three years, our new strategy has focused on day-to-day activities to meet the needs of our partners and customers.

These awards support our teams in delivering the projects announced this year: a state-of-the-art ADC conjugation facility and the expansion of our U.S. laboratory."

PARAGON BIOSERVICES

CATEGORIES WON

Paragon Bioservices, Inc.

Baltimore, MD
www.paragonbioservices.com

+1 410 975 4050
Philip Wills
pwills@paragonbioservices.com
Key locations: Baltimore, MD

DRUG TYPE:
Biopharmaceuticals

DRUG LIFE CYCLE STAGES:
Research & Development: Discovery, Preclinical, Clinical (Phase 1)
Drug Substance Production: Primary Process Development, Drug Substance Production
Formulated Drug Production: Dosage Form Development, Dosage Form Production, Packaging

SERVICES & CAPABILITIES: aseptic fill/finish, cell culture, cell & virus banking, cytotoxic & high potency compounds, fermentation, formulation, injectables, liquids, non-sterile, parenterals (small volume), peptides, process development, purification, proteins, solutions & suspensions, sterile, vaccines

INDIVIDUAL ATTRIBUTE AWARDS: accessible senior management, cultural fit, innovation, on-time, reputation, right first time, state-of-the-art, strength of science

PETER BUZY
President & CFO

"Responsibility to our clients, a passion for science, and our collective need to contribute to better public health – that's what keeps us motivated and excited about the work that we perform. We are driven by our commitment to provide exceptional quality, scientific excellence, and superior customer service. We bring 25 years of experience working with biologics to every client project – from research and process development services to GMP manufacturing for Phase 1-2 clinical trials."

Patheon
A HEALTHIER WORLD. DELIVERED.

CATEGORIES WON

Patheon

Durham, NC
www.patheon.com

+1 919 226 3200
Tom Sellig
tom.sellig@patheon.com
Key locations: Europe, Australia, Asia, North America

DRUG TYPE:
Biopharmaceuticals

DRUG LIFE CYCLE STAGES:
Research & Development: Preclinical, Clinical (Phase 1, Phase 2, Phase 3)
Drug Substance Production: Primary Process Development, Drug Substance Production
Formulated Drug Production: Dosage Form Development, Dosage Form Production, Packaging

SERVICES & CAPABILITIES: aseptic fill/finish, capsules, cartridges, controlled substances, cytotoxic & high potency compounds, generics, injectables, lyophilized products, non-sterile, OTC, parenterals (large volume), parenterals (small volume), peptides, powders (non-sterile), powders (sterile), proteins, semisolids, soft gels, solid dose, solutions & suspensions, sterile, sustained release, syringes (prefilled), vaccines

INDIVIDUAL ATTRIBUTE AWARDS: reputation, right first time

JAMES MULLEN
CEO

"It's an honor to receive the 2016 CMO Leadership Award in these categories. It's rewarding that our clients recognize our commitment to quality, reliability, and scientific capabilities and technical expertise of our people. We work with our clients to develop customized solutions to their development and manufacturing challenges. At Patheon we're committed to forging deeper relationships with clients – working as partners to employ new business models to simplify and shorten time to market."

PCI
Together. Moving Ideas Forward.

CATEGORIES WON

PCI Synthesis

Newburyport, MA
www.pcisynthesis.com

+1 978 462 5555
Derek Richards
derek.richards@pcisynthesis.com
Key locations: Newburyport, MA
Devens, MA

DRUG TYPE:
Pharmaceuticals

DRUG LIFE CYCLE STAGES:
Research & Development: Preclinical, Clinical (Phase 1, Phase 2, Phase 3)
Drug Substance Production: Primary Process Development, Drug Substance Production

SERVICES & CAPABILITIES: capsules, controlled substances, creams & ointments, generics, injectables, liquids, lyophilized products, ophthalmics, solid dose, topicals

INDIVIDUAL ATTRIBUTE AWARDS: accessible senior management, on-time

EDWARD PRICE
President

"PCI Synthesis is the largest drug substance manufacturer in New England and our entire organization is dedicated to helping our partners develop and commercialize their life changing therapies, medical devices, and diagnostics. It is through the true spirit of partnership that great things can be accomplished when people work together. We are honored once again to be recognized as a leading drug substance CMO which we work hard at each and every day."

Pfizer PFIZER CENTRESOURCE
Partnering with our Customers for a Healthier World

CATEGORIES WON

Pfizer CentreSource

Kalamazoo, MI
www.pfizercentresource.com

+1 269 833 5844
Kyle Chisholm
kyle.w.chisholm@pfizer.com
Key locations: Kalamazoo, MI, McPherson, KS, Rocky Mount, NC, U.S.A.; Little Island, Ireland; Ringaskiddy, Ireland

DRUG TYPE:
Pharmaceuticals, Biopharmaceuticals

DRUG LIFE CYCLE STAGES:
Research & Development: Clinical (Phase 2, Phase 3)
Drug Substance Production: Drug Substance Production
Formulated Drug Production: Dosage Form Development, Dosage Form Production, Packaging, Logistics

SERVICES & CAPABILITIES: aseptic fill/finish, capsules, controlled substances, creams & ointments, cytotoxic & high potency compounds, injectables, liquids, lyophilized products, non-sterile, parenterals (large volume), parenterals (small volume), peptides, proteins, semisolids, solid dose, solutions & suspensions, sterile, syringes (prefilled), topicals

INDIVIDUAL ATTRIBUTE AWARDS: accessible senior management, cultural fit, innovation, on-time, reputation, right first time, state-of-the-art, strength of science

CRISTEN GROVE
Director, Contract Manufacturing

"We believe our specialty focus, technical expertise, and customer-centric culture drive significant value for our partners. We are humbled and truly appreciate being recognized for this award the past five years. We look forward to 2016 as we unite Pfizer CentreSource and Hospira One 2 One as a distinct CMO. Our combined contract manufacturing organization brings together the best of Pfizer and Hospira capabilities and we believe that this will allow us to provide a wider array of services and manufacturing technology depth for you, our partners. Pfizer will continue its unwavering commitment to quality, compliance, and supply reliability.

CATEGORIES WON

PharmaCore, Inc.

High Point, NC
www.pharmacore.com

+1 336 841 5250
Cheryl Garr
cgarr@pharmacore.com
Key locations: High Point, NC

DRUG TYPE:
Pharmaceuticals

DRUG LIFE CYCLE STAGES:
Research & Development: Discovery, Preclinical, Clinical (Phase 1, Phase 2, Phase 3)

SERVICES & CAPABILITIES: analytical services, API process development, API manufacture (nGMP & GMP), controlled substances

INDIVIDUAL ATTRIBUTE AWARDS: accessible senior management, cultural fit, innovation, on-time, reputation, right first time, state-of-the-art, strength of science

ROB MADDOX
President

"On behalf of the PharmaCore team, I am honored that we have again been chosen to receive CMO Leadership Awards. We have been recognized in all categories including quality, reliability, compatibility, capability, and expertise; demonstrating our commitment to deliver. We continue to focus on doing things right and adding value to benefit our clients. As our reputation for excellence grows we look forward to new opportunities to showcase our talents and serve our clients"

CATEGORIES WON

Rentschler Biotechnologie GmbH

Laupheim, Germany
www.rentschler.de

+4973927010
Dr. Christoph Winterhalter
christoph.winterhalter@rentschler.de
Key locations: Laupheim, Germany

DRUG TYPE:
Biopharmaceuticals

DRUG LIFE CYCLE STAGES:
Research & Development: Preclinical, Clinical (Phase 1, Phase 2, Phase 3)
Drug Substance Production: Primary Process Development, Drug Substance Production
Formulated Drug Production: Dosage Form Production

SERVICES & CAPABILITIES: aseptic fill/finish, lyophilized products, nonsterile, proteins, solutions & suspensions, sterile, syringes (prefilled)

INDIVIDUAL ATTRIBUTE AWARDS: cultural fit, on-time, right first time, state-of-the-art

CATEGORIES WON

SAI Life Sciences Ltd

Hyderabad, Telangana, India
www.sailife.com

+91 (0)40 6677 7555
Marcel Velterop
marcelv@sailife.com
Key locations: Bidar, Karnataka, Unit 4; Bollaram, Hyderabad Unit 3

DRUG TYPE:
Pharmaceuticals

DRUG LIFE CYCLE STAGES:
Research & Development: Discovery, Preclinical, Clinical (Phase 1, Phase 2, Phase 3)
Drug Substance Production: Primary Process Development, Drug Substance Production
Formulated Drug Production: Dosage Form Development

SERVICES & CAPABILITIES: capsules, cytotoxic & high potency compounds, gels, generics, injectables, parenterals (small volume), solid dose, sustained release

INDIVIDUAL ATTRIBUTE AWARDS: cultural fit, reputation, state-of-the-art

KRISHNA KANUMURI
CEO

"SAI Life Sciences feels honored that, for the 3rd time, our customers have rated us as CMO Leadership winners in the categories of compatibility and reliability. Over the past year SAI has been very focused on improving its organization and systems and continues to refine its performance levels in order to meet the very challenging innovator requirements. This recognition is very motivating for our team members and a sign that we are on the right track."

CATEGORIES WON

Samsung BioLogics

Incheon, South Korea
www.samsungbiologics.com

+82 32 455 3112
Emily Kwon
youyoung.kwon@samsung.com
Key locations: Incheon, Korea (Plants 1, 2, & 3)

DRUG TYPE:
Biopharmaceuticals

DRUG LIFE CYCLE STAGES:
Research & Development: Clinical (Phase 1, Phase 2, Phase 3)
Drug Substance Production: Drug Substance Production
Formulated Drug Production: Dosage Form Production, Packaging, Logistics

SERVICES & CAPABILITIES: aseptic fill/finish, injectables, liquids, lyophilized products, proteins, syringes (prefilled)

INDIVIDUAL ATTRIBUTE AWARDS: accessible senior management, on-time, right first time, state-of-the-art

TH KIM
President & CEO

"It is a great honor to be recognized as the winner of a 2016 CMO Leadership Award. With sustainable growth and successful installation of quality system & culture, Samsung BioLogics has become a strategic manufacturing partner to global big pharmas. With our world's best manufacturing facilities, providing full services through clinical to commercial and drug substance to drug product, we will put our utmost efforts to maximize customer satisfaction."

CATEGORIES WON

Siegfried AG

Zofingen, Argau Switzerland
www.siegfried.ch

+41 62 7461520
Marianne Spaene
marianne.spaene@siegfried.ch
Key locations: Switzerland, France, Germany, China, Malta, Pennsville, NJ, Irvine, CA, U.S.A.

DRUG TYPE:
Pharmaceuticals

DRUG LIFE CYCLE STAGES:
Research & Development: Discovery, Preclinical, Clinical (Phase 1, Phase 2, Phase 3)
Drug Substance Production: Primary Process Development, Drug Substance Production
Formulated Drug Production: Dosage Form Development, Dosage Form Production, Packaging, Logistics

SERVICES & CAPABILITIES: aseptic fill/finish, capsules, cartridges, controlled substances, gels, high containment compounds, injectables, non-sterile, opthalmics, parenterals (large volume), parenterals (small volume), solid dose, solutions & suspensions, sterile, sustained release

INDIVIDUAL ATTRIBUTE AWARDS: accessible senior management, right first time, strength of science

DR. RUDOLF HANKO
CEO

"Recognition in all five categories is a true testament to our entire team. Siegfried has transformed over the past five years to become a leading, integrated drug substance and drug product service partner. We provide products and tailor-made services that support our customers' entire value chain. Whether it's custom development services producing APIs and drug products (oral or sterile) or controlled substances and higher potency you desire, I can assure you, Siegfried is the right partner for you."

CATEGORIES WON

STA, a WuXi AppTec company

Shanghai, China
www.stapharma.com

+1 651 675 2000 Ext. 2324
Yu Lu
yu.lu@wuxiapptec.com
Key locations: Shanghai WaiGaoQiao Free Trade Zone; Jinshan, Shanghai; Changzhou, Jiangsu

DRUG TYPE:
Pharmaceuticals

DRUG LIFE CYCLE STAGES:
Research & Development: Preclinical, Clinical (Phase 1, Phase 2, Phase 3)
Drug Substance Production: Primary Process Development

SERVICES & CAPABILITIES: cytotoxic & high potency compounds, powders (nonsterile), powders (sterile), solid dose

INDIVIDUAL ATTRIBUTE AWARDS: accessible senior management, innovation, right first time, state-of-the-art

MINZHANG CHEN
CEO, Sr. VP

"I'm very proud that WuXi's STA is a 2016 CMO Leadership Award recipient in four categories. As an emerging world-leading CDMO, we strive to provide our customers the highest quality of services with our state-of-the-art facilities, efficient R&D and manufacturing processes, as well as talented people. We look forward to expanding our capabilities and capacities with the newly opened facilities in Changzhou, China to better serve our partners."

VETTER

CATEGORIES WON

Vetter Pharma International GmbH

Ravensburg, Germany
www.vetter-pharma.com

+49 751 3700 0
Oskar Gold
info@vetter-pharma.com
Key locations: Vetter Schuetzenstrasse GMP, Germany; Ravensburg Vetter South GMP, Germany; Vetter Langenargen GMP, Germany; Ravensburg Vetter West, Germany

DRUG TYPE:
Pharmaceuticals, Biopharmaceuticals

DRUG LIFE CYCLE STAGES:
Research & Development: Preclinical, Clinical (Phase 1, Phase 2, Phase 3)
Drug Substance Production: Primary Process Development, Drug Substance Production
Formulated Drug Production: Dosage Form Development, Dosage Form Production, Packaging, Logistics

SERVICES & CAPABILITIES: aseptic fill/finish, cartridges, controlled substances, generics, injectables, liquids, lyophilized products, ophthalmics, parenterals (large volume), parenterals (small volume), peptides, proteins, solutions & suspensions, sterile, sustained release, syringes (pre-filled), vaccines

INDIVIDUAL ATTRIBUTE AWARDS: accessible senior management, innovation, reputation, right first time, state-of-the-art, strength of science

PETER SOELKNER
Managing Director

"Vetter is thrilled to win this award, particularly in four categories of critical importance to our customers. Quality, expertise, capabilities, and compatibility are among the major success factors for our business, and well represent our continuous efforts to perform at a high level, meeting or exceeding customers' expectations. That is the philosophy of Vetter and the goal of our employees. This award is a reflection of the pride we take in achieving superior results."

Xcelience®

CATEGORIES WON

Xcelience

Tampa, FL
www.xcelience.com

+1 813 286 0404
Sharon Burgess
sharon.burgess@xcelience.como
Key locations: Tampa, FL, Quakertown, PA

DRUG TYPE:
Pharmaceuticals

DRUG LIFE CYCLE STAGES:
Research & Development: Preclinical, Clinical (Phase 1, Phase 2, Phase 3)
Formulated Drug Production: Dosage Form Development, Dosage Form Production, Packaging, Logistics

SERVICES & CAPABILITIES: capsules, controlled substances, cytotoxic & high potency compounds, liquids, nonsterile, powders (nonsterile), solid dose, solutions & suspensions, sustained release

INDIVIDUAL ATTRIBUTE AWARDS: accessible senior management, cultural fit, reputation, right first time

DEREK HENNECKE
President & CEO

"We are extremely honored to receive this recognition of excellence from our clients and peers. While we strive to be the best in all that we do, it is the award for quality that resonates the loudest throughout our organization. Quality is the virtue that stands behind every email, every process, and every delivery Xcelience makes. Every other skill we excel at may be traced to our overriding pursuit of quality."

Pharma&Biotech

Lonza

Focused on Your Success

Committed to Global Innovation for Human Health

WINNER 2016 CMO Leadership Awards

Lonza has been a reliable partner in the life sciences industry for over 30 years. Our experience in biological and chemical development and manufacturing has allowed us to create a broad platform of technologies and services for fine chemicals, advanced intermediates, active pharmaceutical ingredients (APIs), functional ingredients, biologics, cell and viral therapies.

We are committed to continued innovation with a focus on future scale-up technologies and emerging markets. Whether you are an established pharmaceutical company or an emerging biotech, Lonza is prepared to meet your outsourcing needs at any scale.

Why Outsource with Lonza?

- Full range of services from preclinical risk assessment to full-scale commercial manufacturing
- Advanced technologies and optimized processes to streamline your product pipeline
- 10 contract development and manufacturing sites worldwide
- Experience with worldwide regulatory authorities
- Track record in meeting accelerated timelines associated with breakthrough therapy designated products
- Dedicated project teams committed to comprehensive and timely communications
- Lean, sustainable processes that minimize waste and environmental risk

For more information, contact us at:
North America: +1 201 316 9200
Europe and Rest of World: +41 61 316 81 11
custom@lonza.com

www.lonza.com/oursites

Bringing the best of

ONE2ONE™ Pfizer PFIZER CENTRESOURCE

together

Let's provide some clarity around how this affects YOU

Our Commitment

We're bringing together the best of our contract manufacturing capabilities to grow our CMO beyond what it would achieve as standalone businesses. That way, we can provide a wider array of services and technologies for you--all with Pfizer's unwavering commitment to quality, compliance and supply reliability.

What's Next

New name, expanded capabilities, same focus: YOU